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FISHER & PAYKEL HEALTHCARE LIMITED

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

FISHER & PAYKEL HEALTHCARE LIMITED, a New Zealand corporation Plaintiff, v. RESMED CORP., a Minnesota corporation, Defendant.	Case No. **'16CV2068 GPC WVG** **COMPLAINT FOR PATENT INFRINGEMENT** **DEMAND FOR JURY TRIAL**

Plaintiff Fisher & Paykel Healthcare Limited ("Plaintiff" or "Fisher & Paykel Healthcare") hereby complains of Defendant ResMed Corp. ("Defendant" or "ResMed") and alleges as follows:

I. THE PARTIES

1. Plaintiff Fisher & Paykel Healthcare Limited is a New Zealand corporation having a principal place of business at 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348, Panmure, Auckland, New Zealand.

2. Upon information and belief, Defendant ResMed Corp. is a corporation organized under the laws of the state of Minnesota with its principal place of business in this district at 9001 Spectrum Center Boulevard, San Diego, California.

II. JURISDICTION AND VENUE

3. Fisher & Paykel Healthcare repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1-2 of this Complaint.

4. Fisher & Paykel Healthcare Inc. is a California corporation having a principal place of business in Irvine, CA.

5. With the authorization of Fisher & Paykel Healthcare Limited, Fisher & Paykel Healthcare Inc. sells in the United States products covered by one or more of the patents asserted herein.

6. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., more particularly, 35 U.S.C. §§ 271 and 281.

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. ResMed resides in California and is subject to personal jurisdiction in California, and has committed the acts complained of in this Judicial District.

9. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), (c), and 1400(b).

III. THE PATENTS-IN-SUIT

10. Fisher & Paykel Healthcare Limited is the owner by assignment of U.S. Patent 8,443,807 entitled "Breathing Assistance Apparatus" ("the '807 patent"), which the United States Patent and Trademark Office lawfully and duly issued on May 21, 2013. A true and correct copy of the '807 patent is attached hereto as Exhibit 1.

11. Fisher & Paykel Healthcare Limited is the owner by assignment of U.S. Patent 8,479,741 entitled "Breathing Assistance Apparatus" ("the '741 patent"), which the United States Patent and Trademark Office lawfully and duly issued on July 9, 2013. A true and correct copy of the '741 patent is attached hereto as Exhibit 2.

12. Fisher & Paykel Healthcare Limited is the owner by assignment of U.S. Patent 8,186,345 entitled "Apparatus for Supplying Gases to a Patient" ("the '345 patent"), which the United States Patent and Trademark Office lawfully and duly issued on May 29, 2012. A true and correct copy of the '345 patent is attached hereto as Exhibit 3.

13. Fisher & Paykel Healthcare Limited is the owner by assignment of U.S. Patent 8,453,641 entitled "Apparatus For Measuring Properties of Gases Supplied to a Patient" ("the '641 patent"), which the United States Patent and Trademark Office lawfully and duly issued on June 4, 2013. A true and correct copy of the '641 patent is attached hereto as Exhibit 4.

14. Fisher & Paykel Healthcare Limited is the owner by assignment of U.S. Patent 9,265,902 entitled "Apparatus For Measuring Properties of Gases Supplied to a Patient" ("the '902 patent"), which the United States Patent and Trademark Office lawfully and duly issued on February 23, 2016. A true and correct copy of the '902 patent is attached hereto as Exhibit 5.

15. Fisher & Paykel Healthcare Limited is the owner by assignment of U.S. Patent 8,550,072 entitled "Apparatus for Delivering Humidified Gases" ("the '072 patent"), which the United States Patent and Trademark Office lawfully and duly issued on October 8, 2013. A true and correct copy of the '072 patent is attached hereto as Exhibit 6.

16. Fisher & Paykel Healthcare Limited is the owner by assignment of U.S. Patent 8,091,547 entitled "Apparatus for Delivering Humidified Gases" ("the '547 patent"), which the United States Patent and Trademark Office lawfully and duly issued on January 10, 2012. A true and correct copy of the '547 patent is attached hereto as Exhibit 7.

17. Fisher & Paykel Healthcare Limited is the owner by assignment of U.S. Patent 7,111,624 entitled "Apparatus for Delivering Humidified Gases" ("the '624 patent"), which the United States Patent and Trademark Office lawfully and duly issued on September 26, 2006. A true and correct copy of the '624 patent is attached hereto as Exhibit 8.

18. Fisher & Paykel Healthcare Limited is the owner by assignment of U.S. Patent 6,398,197 entitled "Water Chamber" ("the '197 patent"), which the United States Patent and Trademark Office lawfully and duly issued on June 4, 2002. A true and correct copy of the '197 patent is attached hereto as Exhibit 9.

IV. DEFENDANTS' ACTIVITIES

19. Upon information and belief, ResMed has made, used, offered to sell, and/or sold within the United States, and/or has imported into the United States, products including at least Continuous Positive Airway Pressure ("CPAP") machines such as ResMed's AirSense 10 Series, including, without limitation, ResMed AirSense 10 AutoSet, Airsense 10 AutoSet for Her, AirSense 10 CPAP, and AirSense 10 Elite (collectively, "S10 CPAP").

20. Upon further information and belief, ResMed has made, used, offered to sell, and/or sold within the United States, and/or has imported into the

United States, products including at least the AirCurve 10 ASV, AirCurve 10 S, AirCurve 10 VAuto, and AirCurve 10 ST (collectively, "AirCurve 10").

21. Upon further information and belief, ResMed has made, used, offered to sell, and/or sold within the United States, and/or has imported into the United States, ClimateLineAir heated air tubing for use with at least the S10 CPAP products.

22. Upon further information and belief, ResMed has made, used, offered to sell, and/or sold within the United States, and/or has imported into the United States, nasal pillow masks, including the Swift FX and the Swift LT masks.

V. CLAIMS FOR PATENT INFRINGEMENT

FIRST CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 8,443,807)

23. Fisher & Paykel Healthcare realleges and reincorporates the allegations set forth in paragraphs 1 through 22.

24. Upon information and belief, ResMed products, including at least the Swift FX products, infringe at least Claims 1, 2, 4, 6, 8, 17, 20, and 21 of the '807 patent under at least 35 U.S.C. § 271(a), (b), and (c).

25. Upon information and belief, ResMed has directly infringed one or more claims of the '807 patent through manufacture use, sale, offer for sale, and/or importation into the United States of masks, including the Swift FX masks.

26. For example, upon information and belief, the Swift FX mask includes all of the limitations of Claim 1 of the '807 patent. The Swift FX mask is a patient interface that includes a mask assembly with a mask body sized and shaped to leave the mouth of the user uncovered by the mask when in use. Two nasal pillows extend from the mask body, and in use these nasal pillows rest in a substantially sealed manner against the openings of the nasal cavity of the user.

There is a ring engaging the mask body, an elbow rotatably engaged with the ring comprising a plurality of vent holes, a tube or conduit extending from the elbow, and a headgear assembly having two side straps that pass down the cheeks to secure the mask body to a face of a user. The headgear assembly also includes a top strap with a buckle to facilitate length adjustment of the top strap and a back strap adjustably connected to at least the top strap or the two side straps. The two side straps are configured to connect and disconnect with the mask assembly while the elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body. The mask assembly is configured to connect to the two side straps, and the top strap connects only with one or more of the side straps and the back strap.

27. ResMed is aware of the ’807 patent, at least in part through written communications from Fisher & Paykel Healthcare on or about February 27, 2015 notifying ResMed of its infringement of this patent.

28. Upon information and belief, ResMed has actively induced others to infringe the ’807 patent by marketing and selling the above masks, knowing and intending that such masks would be used by customers and end users in a manner that infringes the ’807 patent. To that end, ResMed provides instructions and teachings to its customers and end users that such masks be used to infringe the ’807 patent. ResMed’s acts constitute infringement of the ’807 patent in violation of 35 U.S.C. § 271(b).

29. Upon information and belief, ResMed actively induces health-care service providers and users to directly infringe the asserted claims of the ’807 patent. By way of example only, upon information and belief, ResMed actively induces direct infringement of the ’807 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the Swift FX masks.

Upon information and belief, ResMed knew or should have known that these activities would cause direct infringement.

30. Upon information and belief, ResMed's acts constitute contributory infringement of the '807 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, ResMed contributorily infringes because, among other things, ResMed offers to sell and/or sells within the United States, and/or imports into the United States, components of the Swift FX masks that constitute material parts of the invention of the asserted claims of the '807 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by ResMed to be especially made or especially adapted for use in an infringement of the '807 patent.

31. Upon information and belief, ResMed's infringement of the '807 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '807 patent and its infringement thereof, thus acting in reckless disregard of Fisher & Paykel Healthcare's patent rights.

32. As a consequence of ResMed's infringement of the '807 patent, Fisher & Paykel Healthcare has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

33. Upon information and belief, unless enjoined, ResMed, and/or others acting on behalf of ResMed, will continue their infringing acts, thereby causing additional irreparable injury to Fisher & Paykel Healthcare for which there is no adequate remedy at law.

SECOND CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 8,479,741)

34. Fisher & Paykel Healthcare realleges and reincorporates the allegations set forth in paragraphs 1 through 33.

35. Upon information and belief, ResMed products, including at least the Swift LT masks, infringe at least Claims 1-3, 16, 17, 34, and 35 of the '741 patent under 35 U.S.C. § 271(a), (b), or (c).

36. Upon information and belief, ResMed has directly infringed one or more claims of the '741 patent through manufacture use, sale, offer for sale, and/or importation into the United States of the Swift LT masks.

37. For example, upon information and belief, the Swift LT mask includes all of the limitations of Claim 1 of the '741 patent. The Swift LT mask is a patient interface that includes a mask body comprising a substantially flexible plastics material and having two nasal pillows angled toward one another. Each of the nasal pillows has a generally conical portion, a generally cylindrical portion, and an outlet opening. The mask body also includes an inlet opening that is spaced apart from the outlet openings on the nasal pillows and that is within a generally tubular portion of the mask body.

38. Upon information and belief, the Swift LT mask also includes a mask base having a plastics material that is less flexible than the plastics material of the mask body. The mask base has a housing with a through passage, and a proximal portion of the through passage is surrounded by a recess. The recess receives the generally tubular portion of the mask body that defines the mask body inlet opening. Two side arms are removably connected to the mask base, and each side arm is three-dimensionally molded and has a varying cross-sectional thickness.

39. Upon information and belief, the Swift LT mask includes headgear with two side straps of a composite foam material. Each side arm overlaps with and is secured to one of the side straps, and the side strap extends only partially along the side arm to which it is secured.

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40. ResMed is aware of the '741 patent, at least in part through written communications from Fisher & Paykel Healthcare on or about February 27, 2015 notifying ResMed of its infringement of this patent.

41. Upon information and belief, ResMed has actively induced others to infringe the '741 patent. ResMed's acts constitute infringement of the '741 patent in violation of 35 U.S.C. § 271(b).

42. Upon information and belief, ResMed actively induces health-care service providers and users to directly infringe the asserted claims of the '741 patent. By way of example only, upon information and belief, ResMed actively induces direct infringement of the '741 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the Swift LT masks. Upon information and belief, ResMed knew or should have known that these activities would cause direct infringement.

43. Upon information and belief, ResMed's acts constitute contributory infringement of the '741 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, ResMed contributorily infringes because, among other things, ResMed offers to sell and/or sells within the United States, and/or imports into the United States, components of the Swift LT masks that constitute material parts of the invention of the asserted claims of the '741 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by ResMed to be especially made or especially adapted for use in an infringement of the '741 patent.

44. Upon further information and belief, such components are used by ResMed in connection with the refurbishing, servicing and/or use of infringing Swift LT masks in the United States, thereby constituting direct infringement of the asserted claims of the '741 patent.

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45. Upon information and belief, ResMed's infringement of the '741 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '741 patent and its infringement thereof, thus acting in reckless disregard of Fisher & Paykel Healthcare's patent rights.

46. As a consequence of ResMed's infringement of the '741 patent, Fisher & Paykel Healthcare has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

47. Upon information and belief, unless enjoined, ResMed, and/or others acting on behalf of ResMed, will continue their infringing acts, thereby causing additional irreparable injury to Fisher & Paykel Healthcare for which there is no adequate remedy at law.

THIRD CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 8,186,345)

48. Fisher & Paykel Healthcare realleges and reincorporates the allegations set forth in paragraphs 1 through 47.

49. Upon information and belief, ResMed products, including at least the S10 CPAP, AirCurve 10, and ClimateLineAir products, infringe at least Claims 1 and 3 of the '345 patent under 35 U.S.C. § 271(a), (b), or (c).

50. Upon information and belief, ResMed has directly infringed the asserted claims of the '345 patent through manufacture use, sale, offer for sale, and/or importation into the United States of the S10 CPAP, AirCurve 10, and ClimateLineAir products.

51. For example, upon information and belief, the AirSense 10 with ClimateLine Air tubing includes all of the limitations of Claim 1 of the '345 patent. Upon information and belief, the AirSense 10 with Climate Line Air tubing is an apparatus for supplying gases to a patient. It includes a gases

supply and a tube with a heater wire for heating the conduit. The heater wire is located around the outside of the tube. The circuitry of the ClimateLine Air tube includes a thermistor, which has a characteristic impedance. The user manual for the AirSense 10 indicates that this device has a controller for controlling the heating of the heater wire. The controller can automatically identify the conduit attached by using the resistance from the thermistor at room temperature to determine the type of delivery conduit attached.

52. ResMed is aware of the ’345 patent, at least in part through written communications from Fisher & Paykel Healthcare on or about February 22, 2016 notifying ResMed of its infringement of this patent.

53. Upon information and belief, ResMed has actively induced others to infringe the ’345 patent. ResMed’s acts constitute infringement of the ’345 patent in violation of 35 U.S.C. § 271(b).

54. Upon information and belief, ResMed actively induces health-care service providers and users to directly infringe the asserted claims of the ’345 patent. By way of example only, upon information and belief, ResMed actively induces direct infringement of the ’345 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the S10 CPAP, AirCurve 10, and ClimateLineAir products.

55. Upon information and belief, ResMed knew or should have known that these activities would cause direct infringement.

56. Upon information and belief, ResMed’s acts constitute contributory infringement of the ’345 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, ResMed contributorily infringes because, among other things, ResMed offers to sell and/or sells within the United States, and/or imports into the United States, components of the S10 CPAP, AirCurve 10, and ClimateLineAir products that constitute material parts of the invention of the

asserted claims of the '345 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by ResMed to be especially made or especially adapted for use in an infringement of the '345 patent.

57. Upon further information and belief, such components are used by ResMed in connection with the refurbishing, servicing and/or use of infringing S10 CPAP, AirCurve 10, and ClimateLineAir products in the United States, thereby constituting direct infringement of the asserted claims of the '345 patent.

58. Upon information and belief, ResMed's infringement of the '345 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '345 patent and its infringement thereof, thus acting in reckless disregard of Fisher & Paykel Healthcare's patent rights.

59. As a consequence of ResMed's patent infringement of the '345 patent, Fisher & Paykel Healthcare has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

60. Upon information and belief, unless enjoined, ResMed, and/or others acting on behalf of ResMed, will continue their infringing acts, thereby causing additional irreparable injury to Fisher & Paykel Healthcare for which there is no adequate remedy at law.

FOURTH CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 8,453,641)

61. Fisher & Paykel Healthcare realleges and reincorporates the allegations set forth in paragraphs 1 through 60.

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62. Upon information and belief, ResMed products, including at least the S10 CPAP, AirCurve 10, and ClimateLineAir products, infringe at least Claims 1 5, and 6 of the ’641 patent under 35 U.S.C. § 271(a), (b), or (c).

63. Upon information and belief, ResMed has directly infringed the asserted claims of the ’641 patent through manufacture use, sale, offer for sale, and/or importation into the United States of the S10 CPAP, AirCurve 10, and ClimateLineAir products.

64. For example, upon information and belief, the AirSense 10 with ClimateLine Air tubing includes all of the limitations of Claim 1 of the ‘641 patent. The AirSense 10 is an apparatus for measuring the properties of gases being supplied to a patient. It includes a gases supply and a tube that includes a heater wire for heating the tube. The heater wire is located around the outside of the tube. The tube has two ends, and the heater wire extends longitudinally along the tube from the first end to the second end of the tube. The heater wire forms part of the circuit of the AirSense 10 device and is measured by a controller to determine properties of the gases, including temperature and/or relative humidity. The electrical circuit has two portions, one that is located near the first end of the tube and the other that is located near the second end of the tube. The two portions of the electrical circuit are in electrical communication with each other through a thermistor that is electrically connected to the contacts at the gases supply end of the electrical circuit. The change in current from the thermistor is used to determine temperature of the gases as it varies.

65. ResMed is aware of the ’641 patent, at least in part through written communications from Fisher & Paykel Healthcare on or about February 22, 2016 notifying ResMed of its infringement of this patent.

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66. Upon information and belief, ResMed has actively induced others to infringe the '641 patent. ResMed's acts constitute infringement of the '641 patent in violation of 35 U.S.C. § 271(b).

67. Upon information and belief, ResMed actively induces health-care service providers and users to directly infringe the asserted claims of the '641 patent. By way of example only, upon information and belief, ResMed actively induces direct infringement of the '641 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the S10 CPAP, AirCurve 10, and ClimateLineAir products.

68. Upon information and belief, ResMed knew or should have known that these activities would cause direct infringement.

69. Upon information and belief, ResMed's acts constitute contributory infringement of the '641 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, ResMed contributorily infringes because, among other things, ResMed offers to sell and/or sells within the United States, and/or imports into the United States, components of the S10 CPAP, AirCurve 10, and ClimateLineAir products that constitute material parts of the invention of the asserted claims of the '641 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by ResMed to be especially made or especially adapted for use in an infringement of the '641 patent.

70. Upon further information and belief, such components are used by ResMed in connection with the refurbishing, servicing and/or use of infringing S10 CPAP, AirCurve 10, and ClimateLineAir products in the United States, thereby constituting direct infringement of the asserted claims of the '641 patent.

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71. Upon information and belief, ResMed's infringement of the '641 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '641 patent and its infringement thereof, thus acting in reckless disregard of Fisher & Paykel Healthcare's patent rights.

72. As a consequence of ResMed's patent infringement of the '641 patent, Fisher & Paykel Healthcare has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

73. Upon information and belief, unless enjoined, ResMed, and/or others acting on behalf of ResMed, will continue their infringing acts, thereby causing additional irreparable injury to Fisher & Paykel Healthcare for which there is no adequate remedy at law.

FIFTH CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 9,265,902)

74. Fisher & Paykel Healthcare realleges and reincorporates the allegations set forth in paragraphs 1 through 73.

75. Upon information and belief, ResMed products, including at least the S10 CPAP, AirCurve 10, and ClimateLineAir products, infringe at least Claims 7, 11, and 12of the '902 patent under 35 U.S.C. § 271(a), (b), or (c).

76. Upon information and belief, ResMed has directly infringed the asserted claims of the '902 patent through manufacture use, sale, offer for sale, and/or importation into the United States of the S10 CPAP, AirCurve 10, and ClimateLineAir products.

77. For example, upon information and belief, the AirSense 10 with ClimateLine Air includes all of the limitations of Claim 7 of the '902 patent. The AirSense 10 is configured to supply a stream of gases to a patient. It includes a gases supply, a tube configured to connect to the gases supply and to

deliver the stream of gases to the patient, and a heater wire extending through a length of the tube. An electrical circuit connected to the wire includes a thermistor, and current flows through the thermistor and wire to a controller. Based on the current, the controller can determine at least the temperature of the gases and can adjust for patient comfort or therapeutic setting. The thermistor is positioned within the stream of gases. An overmolding encloses part of the electrical circuit and extends into the middle of the tube.

78. ResMed is aware of the ’902 patent, at least in part through written communications from Fisher & Paykel Healthcare on or about February 22, 2016 notifying ResMed of its infringement of this patent.

79. Upon information and belief, ResMed has actively induced others to infringe the ’902 patent. ResMed’s acts constitute infringement of the ’902 patent in violation of 35 U.S.C. § 271(b).

80. Upon information and belief, ResMed actively induces health-care service providers and users to directly infringe the asserted claims of the ’902 patent. By way of example only, upon information and belief, ResMed actively induces direct infringement of the ’902 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the S10 CPAP, AirCurve 10, and ClimateLineAir products.

81. Upon information and belief, ResMed knew or should have known that these activities would cause direct infringement.

82. Upon information and belief, ResMed’s acts constitute contributory infringement of the ’902 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, ResMed contributorily infringes because, among other things, ResMed offers to sell and/or sells within the United States, and/or imports into the United States, components of the S S10 CPAP, AirCurve 10, and ClimateLineAir products that constitute material parts of the invention of

the asserted claims of the '902 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by ResMed to be especially made or especially adapted for use in an infringement of the '902 patent.

83. Upon further information and belief, such components are used by ResMed in connection with the refurbishing, servicing and/or use of infringing S10 CPAP, AirCurve 10, and ClimateLineAir products in the United States, thereby constituting direct infringement of the asserted claims of the '902 patent.

84. Upon information and belief, ResMed's infringement of the '902 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '902 patent and its infringement thereof, thus acting in reckless disregard of Fisher & Paykel Healthcare's patent rights.

85. As a consequence of ResMed's patent infringement of the '902 patent, Fisher & Paykel Healthcare has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

86. Upon information and belief, unless enjoined, ResMed, and/or others acting on behalf of ResMed, will continue their infringing acts, thereby causing additional irreparable injury to Fisher & Paykel Healthcare for which there is no adequate remedy at law.

SIXTH CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 8,550,072)

87. Fisher & Paykel Healthcare realleges and reincorporates the allegations set forth in paragraphs 1 through 86.

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88. Upon information and belief, ResMed products, including at least the S10 CPAP and AirCurve 10 products, infringe at least Claims 6, 12, and 13 of the ’072 patent under 35 U.S.C. § 271(a), (b), or (c).

89. Upon information and belief, ResMed has directly infringed the asserted claims of the ’072 patent through the manufacture, use, sale, offer for sale, and/or importation into the United States of the S10 CPAP and AirCurve 10 products.

90. For example, upon information and belief, the AirSense 10 includes all of the limitations of Claim 6 of the ‘072 patent. The AirSense 10 is an apparatus for use in humidified gases delivery treatment. It includes a blower for generating a supply of pressurised gases. It includes a pressurised gases outlet in fluid connection with the pressurised gases supply and adapted to make a separate fluid connection with an inlet of a water chamber to provide gases flow to the chamber. It includes a humidified gases return adapted to make a separate fluid connection with an outlet of the water chamber in order to receive humidified gases from the water chamber, and it is adjacent to and aligned with the pressurised gases outlet. These two fluid connections are made by a single motion. The AirSense 10 also includes a patient outlet in fluid connection with the humidified gases return to receive humidified gases from the humidified gases return and to provide humidified gases to the patient outlet. This patient outlet is in fluid connection with or adapted to make fluid connection with a breathing conduct for delivery of humidified gases to a patient.

91. ResMed is aware of the ’072 patent, at least in part through written communications from Fisher & Paykel Healthcare on or about October 1, 2015 notifying ResMed of its infringement of this patent.

92. Upon information and belief, ResMed has actively induced others to infringe the ’072 patent. ResMed’s acts constitute infringement of the ’072 patent in violation of 35 U.S.C. § 271(b).

93. Upon information and belief, ResMed actively induces health-care service providers and users to directly infringe the asserted claims of the '072 patent. By way of example only, upon information and belief, ResMed actively induces direct infringement of the '072 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of S10 CPAP and AirCurve 10 products.

94. Upon information and belief, ResMed knew or should have known that these activities would cause direct infringement.

95. Upon information and belief, ResMed's acts constitute contributory infringement of the '072 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, ResMed contributorily infringes because, among other things, ResMed offers to sell and/or sells within the United States, and/or imports into the United States, components of S10 CPAP and AirCurve 10 products that constitute material parts of the invention of the asserted claims of the '072 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by ResMed to be especially made or especially adapted for use in an infringement of the '072 patent.

96. Upon further information and belief, such components are used by ResMed in connection with the refurbishing, servicing and/or use of infringing S10 CPAP and AirCurve 10 products in the United States, thereby constituting direct infringement of the asserted claims of the '072 patent.

97. Upon information and belief, ResMed's infringement of the '072 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '072 patent and its infringement thereof, thus acting in reckless disregard of Fisher & Paykel Healthcare's patent rights.

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98. As a consequence of ResMed's patent infringement of the '072 patent, Fisher & Paykel Healthcare has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

99. Upon information and belief, unless enjoined, ResMed, and/or others acting on behalf of ResMed, will continue their infringing acts, thereby causing additional irreparable injury to Fisher & Paykel Healthcare for which there is no adequate remedy at law.

SEVENTH CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 8,091,547)

100. Fisher & Paykel Healthcare realleges and reincorporates the allegations set forth in paragraphs 1 through 99.

101. Upon information and belief, ResMed products, including at least the S10 CPAP and AirCurve 10 products, infringe at least Claims 24 and 25 of the '547 patent under 35 U.S.C. § 271(a), (b), or (c).

102. Upon information and belief, ResMed has directly infringed the asserted claims of the '547 patent through the manufacture, use, sale, offer for sale, and/or importation into the United States of the S10 CPAP and AirCurve 10 products.

103. For example, upon information and belief, the AirSense 10 includes all of the limitations of Claim 24 of the '547 patent. The AirSense 10 is a gas humidification apparatus. It includes a humidification chamber with a base. It has a housing with a source gases outlet adapted to make a separable fluid connection with an inlet of the humidification chamber in order to provide gases flow into the humidification chamber. The housing also has a humidified gases inlet adapted to make a separable fluid connection with an outlet of the humidification chamber in order to receive humidified gases from the humidification chamber. The humidified gases outlet is in fluid communication

with the humidified gases inlet and is adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient. The housing also includes a heater configured to vaporize liquid water in the humidification chamber to provide water vapor to gases flowing through the humidification chamber. The housing is adapted to accommodate the humidification chamber, which is removable and engageable with the housing via a single motion. The single motion of engagement disposes the base of the humidification chamber adjacent the heater. The single motion also makes or breaks the separable connection between the source gases outlet and the humidification chamber inlet and the separable connection between the humidified gases inlet and the humidification chamber outlet.

104. ResMed is aware of the ’547 patent, at least in part through written communications from Fisher & Paykel Healthcare on or about October 1, 2015 notifying ResMed of its infringement of this patent.

105. Upon information and belief, ResMed has actively induced others to infringe the ’547 patent. ResMed’s acts constitute infringement of the ’547 patent in violation of 35 U.S.C. § 271(b).

106. Upon information and belief, ResMed actively induces health-care service providers and users to directly infringe the asserted claims of the ’547 patent. By way of example only, upon information and belief, ResMed actively induces direct infringement of the ’547 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of S10 CPAP and AirCurve 10 products.

107. Upon information and belief, ResMed knew or should have known that these activities would cause direct infringement.

108. Upon information and belief, ResMed’s acts constitute contributory infringement of the ’547 patent in violation of 35 U.S.C. § 271(c). Upon

information and belief, ResMed contributorily infringes because, among other things, ResMed offers to sell and/or sells within the United States, and/or imports into the United States, components of S10 CPAP and AirCurve 10 products that constitute material parts of the invention of the asserted claims of the '547 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by ResMed to be especially made or especially adapted for use in an infringement of the '547 patent.

109. Upon further information and belief, such components are used by ResMed in connection with the refurbishing, servicing and/or use of infringing S10 CPAP and AirCurve 10 products in the United States, thereby constituting direct infringement of the asserted claims of the '547 patent.

110. Upon information and belief, ResMed's infringement of the '547 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '547 patent and its infringement thereof, thus acting in reckless disregard of Fisher & Paykel Healthcare's patent rights.

111. As a consequence of ResMed's patent infringement of the '547 patent, Fisher & Paykel Healthcare has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

112. Upon information and belief, unless enjoined, ResMed, and/or others acting on behalf of ResMed, will continue their infringing acts, thereby causing additional irreparable injury to Fisher & Paykel Healthcare for which there is no adequate remedy at law.

EIGHTH CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 7,111,624)

113. Fisher & Paykel Healthcare realleges and reincorporates the allegations set forth in paragraphs 1 through 112.

114. Upon information and belief, ResMed products, including at least the S10 CPAP and AirCurve 10 products, infringe at least Claims 1-3 and 7 of the '624 patent under 35 U.S.C. § 271(a), (b), or (c).

115. Upon information and belief, ResMed has directly infringed the asserted claims of the '624 patent through the manufacture, use, sale, offer for sale, and/or importation into the United States of the S10 CPAP and AirCurve 10 products.

116. ResMed is aware of the '624 patent, at least in part through written communications from Fisher & Paykel Healthcare on or about October 1, 2015 notifying ResMed of its infringement of this patent.

117. For example, upon information and belief, the AirSense 10 includes all of the limitations of Claim 1 of the '624 patent. The AirSense 10 is an apparatus for use in humidified gases delivery treatment. It has a housing that has a pressurised gases supply within it. A pressurised gases outlet in the housing is in fluid connection with the pressurised gases supply and is adapted to make fluid connection with an inlet of a humidifier in order to provide gases flow to the humidifier. A humidified gases return in the housing is adapted to make fluid connection with an outlet of the humidifier in order to receive humidified gases from the humidifier. A patient outlet in the housing is in fluid connection with the humidified gases return in order to receive humidified gases and to provide humidified gases to the patient outlet. The patient outlet is in fluid communication with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient.

118. Upon information and belief, ResMed has actively induced others to infringe the '624 patent. ResMed's acts constitute infringement of the '624 patent in violation of 35 U.S.C. § 271(b).

119. Upon information and belief, ResMed actively induces health-care service providers and users to directly infringe the asserted claims of the

'624 patent. By way of example only, upon information and belief, ResMed actively induces direct infringement of the '624 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of S10 CPAP and AirCurve 10 products.

120. Upon information and belief, ResMed knew or should have known that these activities would cause direct infringement.

121. Upon information and belief, ResMed's acts constitute contributory infringement of the '624 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, ResMed contributorily infringes because, among other things, ResMed offers to sell and/or sells within the United States, and/or imports into the United States, components of S10 CPAP and AirCurve 10 products that constitute material parts of the invention of the asserted claims of the '624 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by ResMed to be especially made or especially adapted for use in an infringement of the '624 patent.

122. Upon further information and belief, such components are used by ResMed in connection with the refurbishing, servicing and/or use of infringing S10 CPAP and AirCurve 10 products in the United States, thereby constituting direct infringement of the asserted claims of the '624 patent.

123. Upon information and belief, ResMed's infringement of the '624 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '624 patent and its infringement thereof, thus acting in reckless disregard of Fisher & Paykel Healthcare's patent rights.

124. As a consequence of ResMed's patent infringement of the '624 patent, Fisher & Paykel Healthcare has suffered and will continue to suffer

irreparable harm and injury, including monetary damages in an amount to be determined at trial.

125. Upon information and belief, unless enjoined, ResMed, and/or others acting on behalf of ResMed, will continue their infringing acts, thereby causing additional irreparable injury to Fisher & Paykel Healthcare for which there is no adequate remedy at law.

NINTH CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 6,398,197)

126. Fisher & Paykel Healthcare realleges and reincorporates the allegations set forth in paragraphs 1 through 125.

127. Upon information and belief, ResMed products, including at least the S10 CPAP and AirCurve 10 products, infringe at least Claim 1 of the '197 patent under 35 U.S.C. § 271(a), (b), or (c).

128. Upon information and belief, ResMed has directly infringed the asserted claims of the '197 patent through the manufacture, use, sale, offer for sale, and/or importation into the United States of the S10 CPAP and AirCurve 10 products.

129. For example, upon information and belief, the AirSense 10 includes all of the limitations of Claim 1 of the '197 patent. It includes a water chamber adapted for use in conjunction with a heater base. The water chamber has a horizontally oriented gases inlet in a wall. There is an elongate flow tube extending into the water chamber from the inner periphery of the gases inlet, and an inlet end of the elongate flow tube covering the inlet. An outlet end of the elongate flow tube is spaced from the wall of the water chamber. In use, the elongate flow tube receives at the inlet end gases supplied to the gases inlet. The gases pass through the elongate flow tube and exit the flow tube at the outlet end distant from the wall.

/ / /

130. ResMed is aware of the '197 patent, at least in part through written communications from Fisher & Paykel Healthcare on or about October 1, 2015 notifying ResMed of its infringement of this patent.

131. Upon information and belief, ResMed has actively induced others to infringe the '197 patent. ResMed's acts constitute infringement of the '197 patent in violation of 35 U.S.C. § 271(b).

132. Upon information and belief, ResMed actively induces health-care service providers and users to directly infringe the asserted claims of the '197 patent. By way of example only, upon information and belief, ResMed actively induces direct infringement of the '197 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of S10 CPAP and AirCurve 10 products.

133. Upon information and belief, ResMed knew or should have known that these activities would cause direct infringement.

134. Upon information and belief, ResMed's acts constitute contributory infringement of the '197 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, ResMed contributorily infringes because, among other things, ResMed offers to sell and/or sells within the United States, and/or imports into the United States, components of S10 CPAP and AirCurve 10 products that constitute material parts of the invention of the asserted claims of the '197 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by ResMed to be especially made or especially adapted for use in an infringement of the '197 patent.

135. Upon further information and belief, such components are used by ResMed in connection with the refurbishing, servicing and/or use of infringing S10 CPAP and AirCurve 10 products in the United States, thereby constituting direct infringement of the asserted claims of the '197 patent.

136. Upon information and belief, ResMed's infringement of the '197 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '197 patent and its infringement thereof, thus acting in reckless disregard of Fisher & Paykel Healthcare's patent rights.

137. As a consequence of ResMed's patent infringement of the '197 patent, Fisher & Paykel Healthcare has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

138. Upon information and belief, unless enjoined, ResMed, and/or others acting on behalf of ResMed, will continue their infringing acts, thereby causing additional irreparable injury to Fisher & Paykel Healthcare for which there is no adequate remedy at law.

VI. PRAYER FOR RELIEF

1. WHEREFORE, Plaintiff Fisher & Paykel Healthcare prays for judgment and seeks relief as follows:

(1) Pursuant to 35 U.S.C. § 271, a determination that ResMed and its officers, agents, servants, employees, attorneys and all others in active concert and/or participation with them have infringed each of the '807, '741, '345, '641, '902, '072, '547, '624, and '197 patents through the manufacture, use, importation, offer for sale, and/or sale of infringing products and/or any of the other acts prohibited by 35 U.S.C. § 271;

(2) Pursuant to 35 U.S.C. § 283, an injunction enjoining ResMed and its officers, agents, servants, employees, attorneys and all others in active concert and/or participation with them from infringing the '807, '741, '345, '641, '902, '072, '547, '624, and '197 patents through the manufacture, use, importation, offer for sale, and/or sale of infringing products and/or any of the

other acts prohibited by 35 U.S.C. § 271, including preliminary and permanent injunctive relief;

(3) Pursuant to 35 U.S.C. § 284, an award of compensating Fisher & Paykel Healthcare for ResMed's infringement of the '807, '741, '345, '641, '902, '072, '547, '624, and '197 patents through payment of not less than a reasonable royalty on ResMed's sales of infringing products;

(4) Pursuant to 35 U.S.C. § 284, an award increasing damages up to three times the amount found or assessed by the jury for ResMed's infringement of each of the '807, '741, '345, '641, '902, '072, '547, '624, and '197 patents in view of the willful and deliberate nature of the infringement;

(5) Pursuant to 35 U.S.C. § 285, a finding that this is an exceptional case, and an award of reasonable attorney's fees and non-taxable costs;

(6) An assessment of prejudgment and post-judgment interest and costs against ResMed, together with an award of such interest and costs, pursuant to 35 U.S.C. § 284;

(7) An award of taxable costs; and

(8) That Fisher & Paykel Healthcare be granted such other and further relief as the Court deems equitable and just in the circumstances.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 16, 2016

By: */s/ Sheila N. Swaroop*

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DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff Fisher & Paykel Healthcare Limited demands a trial by jury of all issues raised by the pleadings which are triable by jury.

Dated: August 16, 2016

By: */s/ Sheila N. Swaroop*

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EXHIBIT 1

US008443807B2

(12) **United States Patent**
McAuley et al.

(10) **Patent No.: US 8,443,807 B2**
(45) **Date of Patent: May 21, 2013**

(54) **BREATHING ASSISTANCE APPARATUS**

(75) Inventors: **Alastair Edwin McAuley**, Auckland (NZ); **Oliver Gleeson**, Auckland (NZ); **Evan Stuart Erstich**, Auckland (NZ); **Simon Eric Freeman**, Auckland (NZ); **Neil Glen Davies**, Auckland (NZ); **Stephen John Schoenberg**, Auckland (NZ); **Kamman Law**, Auckland (NZ); **Craig Robert Prentice**, Auckland (NZ)

(73) Assignee: **Fisher & Paykel Healthcare Limited**, Auckland (NZ)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 932 days.

(21) Appl. No.: **12/307,993**

(22) PCT Filed: **Jul. 13, 2007**

(86) PCT No.: **PCT/NZ2007/000185**
§ 371 (c)(1),
(2), (4) Date: **Jun. 17, 2009**

(87) PCT Pub. No.: **WO2008/007985**
PCT Pub. Date: **Jan. 17, 2008**

(65) **Prior Publication Data**

US 2010/0000537 A1 Jan. 7, 2010

(30) **Foreign Application Priority Data**

Jul. 14, 2006 (NZ) 548575
Nov. 6, 2006 (NZ) 551103

(51) **Int. Cl.**
A61M 11/00 (2006.01)

(52) **U.S. Cl.**
USPC **128/207.18**; 128/206.24; 128/207.11; 128/207.13

(58) **Field of Classification Search**
USPC 128/207.18, 206.21, 206.24, 206.27, 128/207.11, 207.13
See application file for complete search history.

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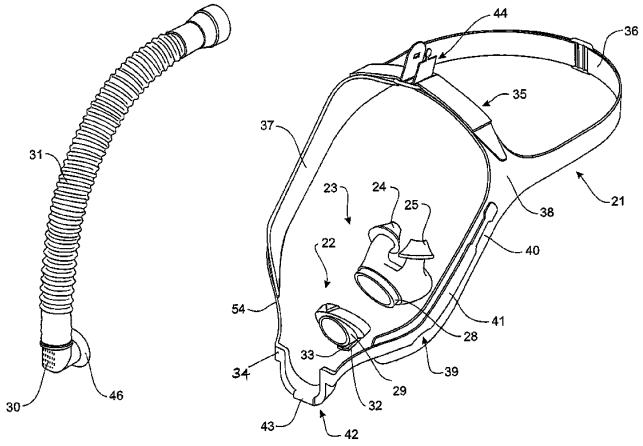
Primary Examiner — Steven Douglas
(74) *Attorney, Agent, or Firm* — Knobbe, Martens Olson & Bear LLP

(57) **ABSTRACT**

Headgear for use with a respiratory mask is described. The headgear comprises a continuous and substantially curved elongate member extending in use below a user's nose and at least two headgear straps capable of attachment to the ends of the elongate member. A mask attachment on the elongate member is disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask. The attachment is capable of receiving the mask.

29 Claims, 21 Drawing Sheets



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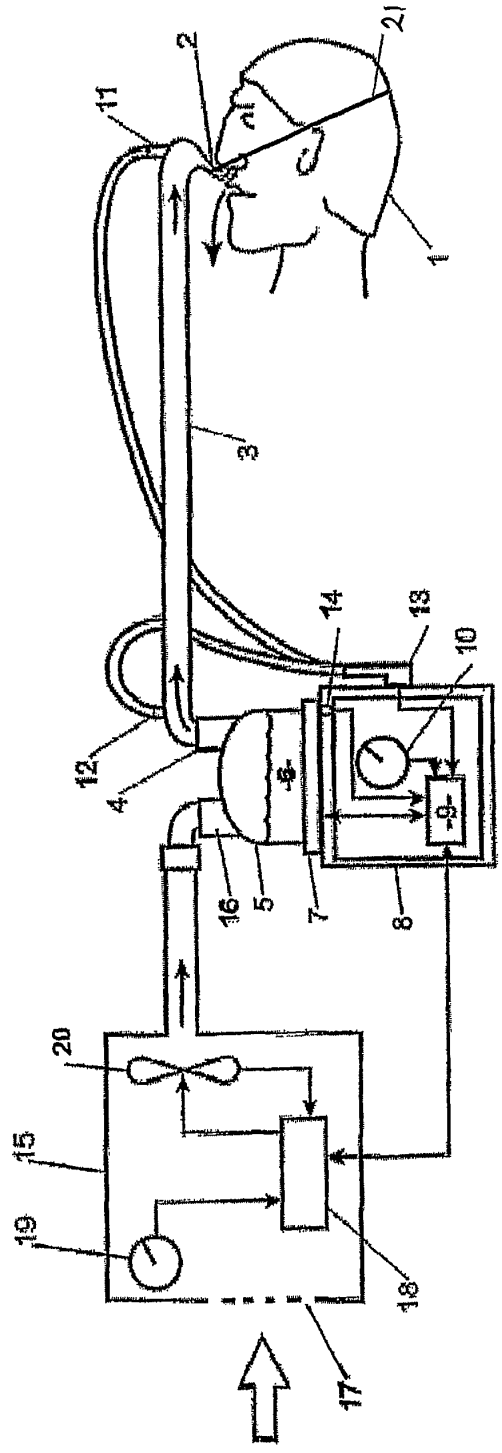

FIGURE 1

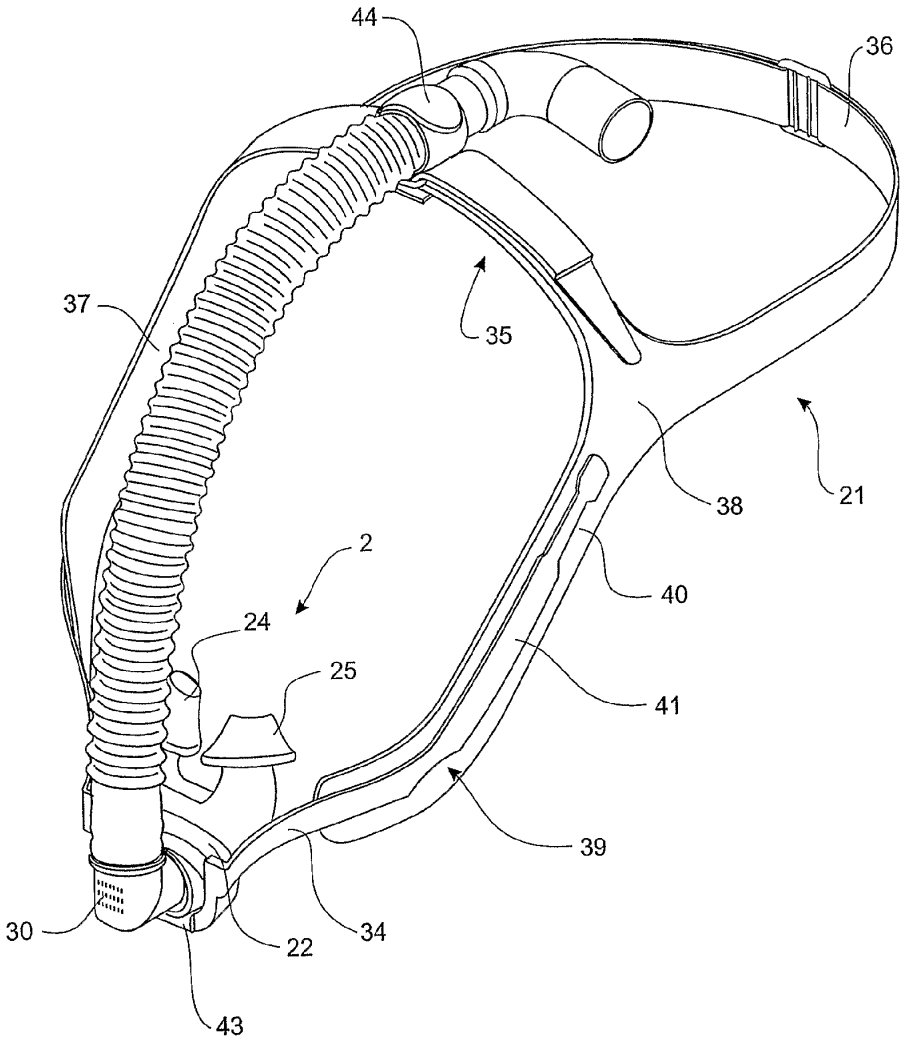

FIGURE 2

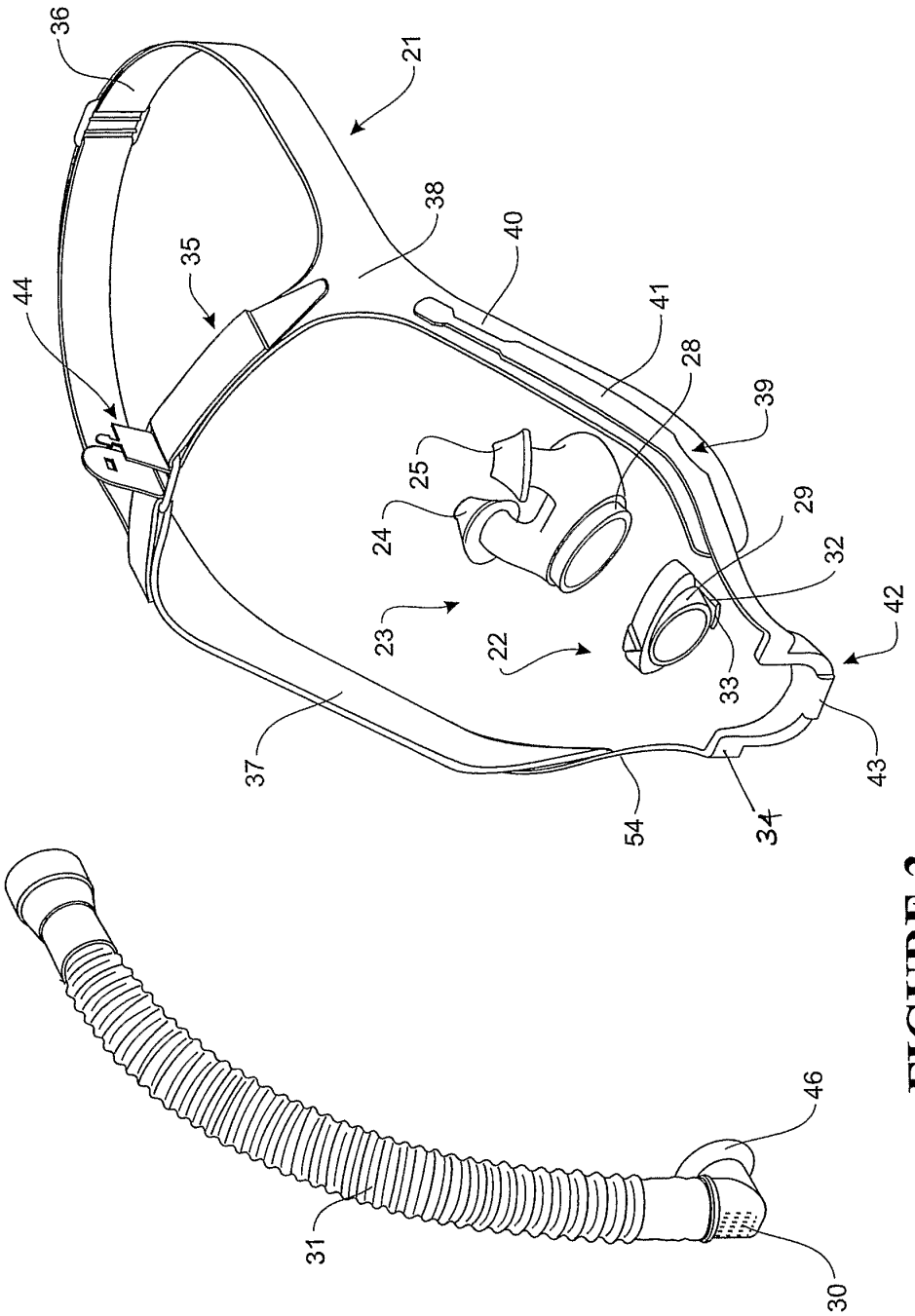

FIGURE 3

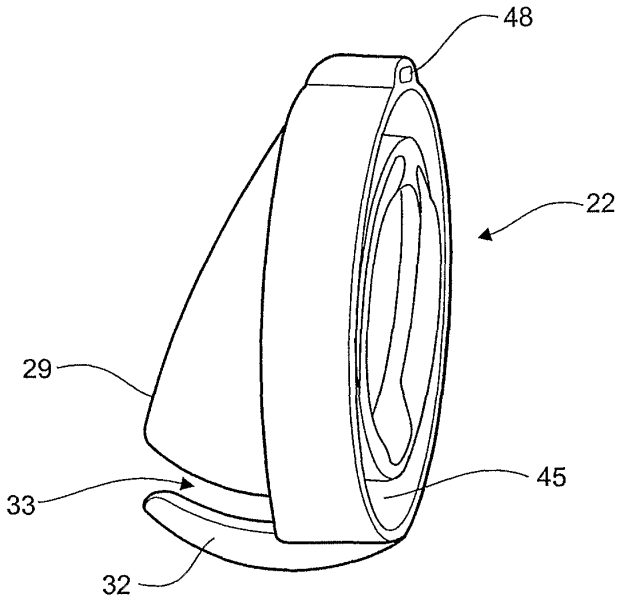

FIGURE 4

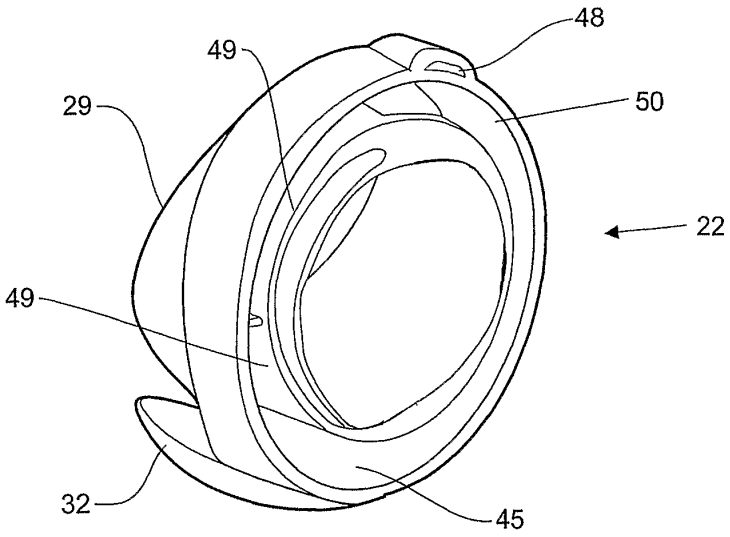

FIGURE 5

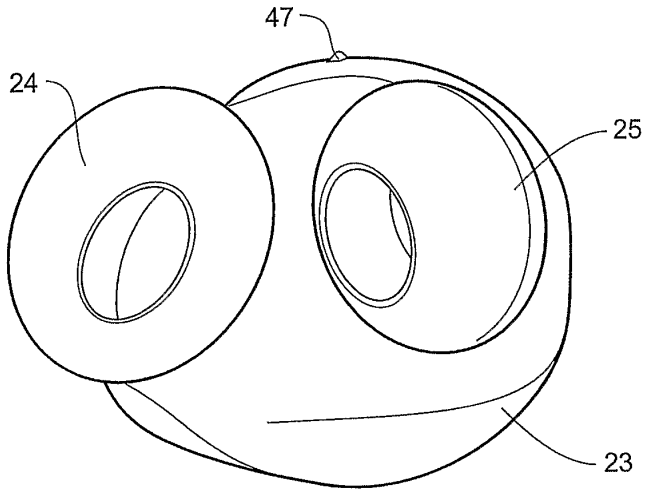

FIGURE 6

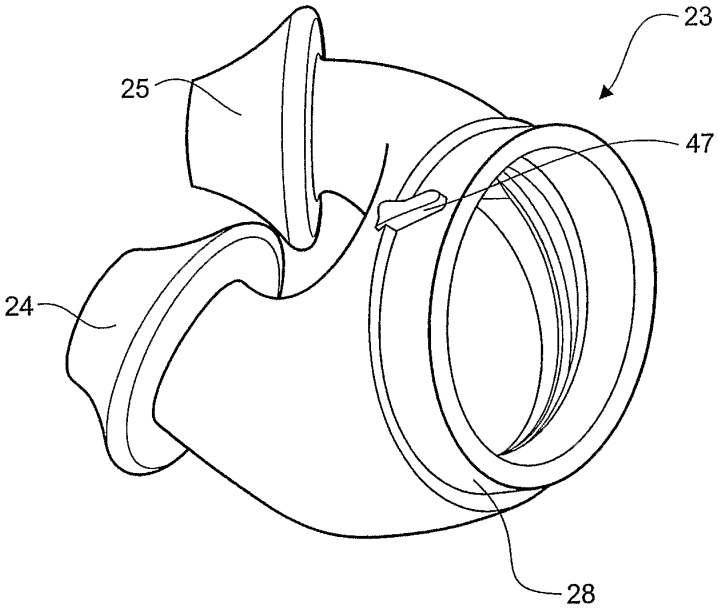

FIGURE 7

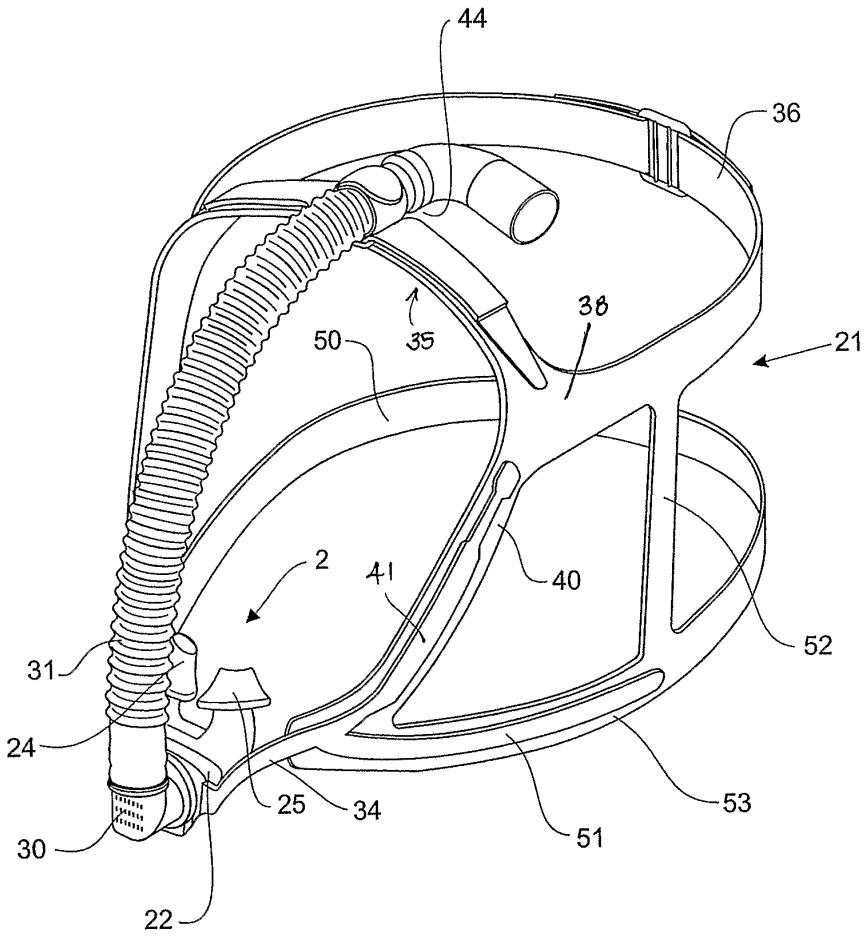

FIGURE 8

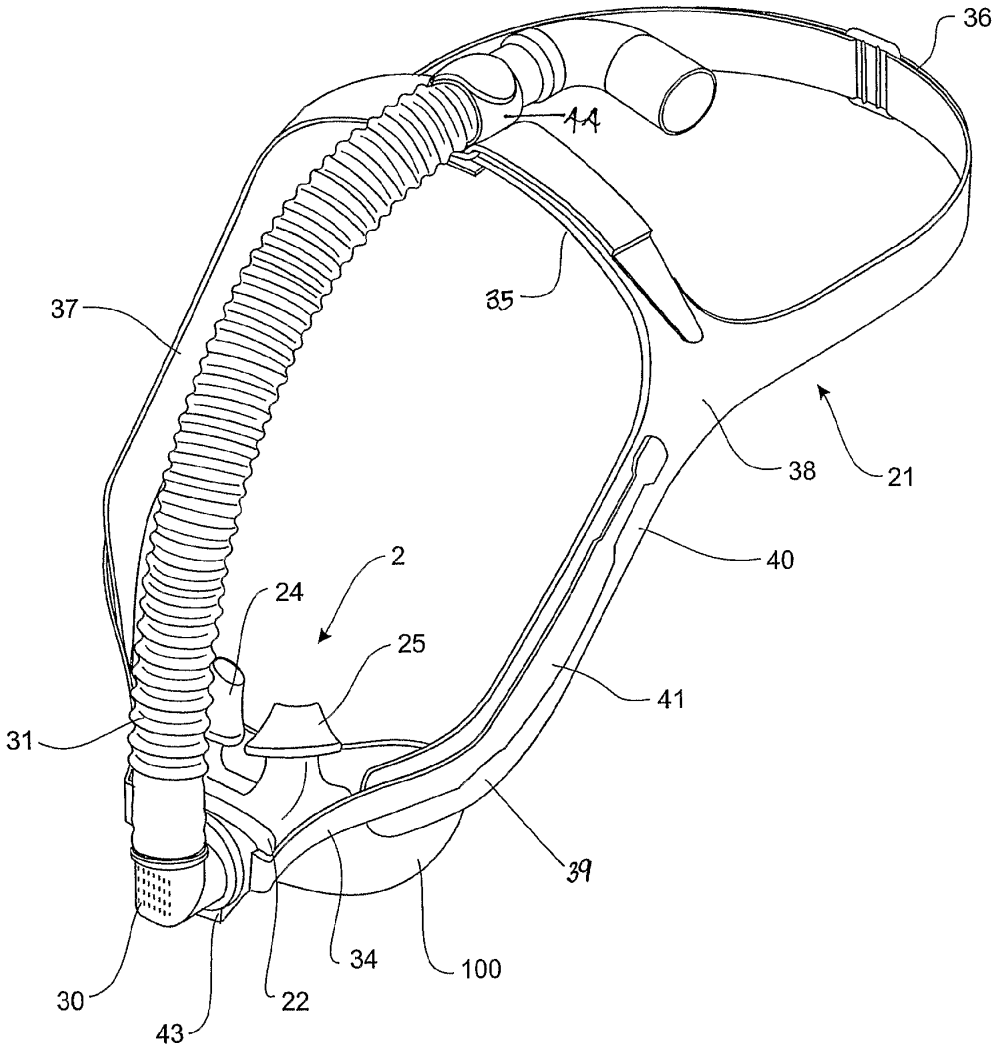

FIGURE 9

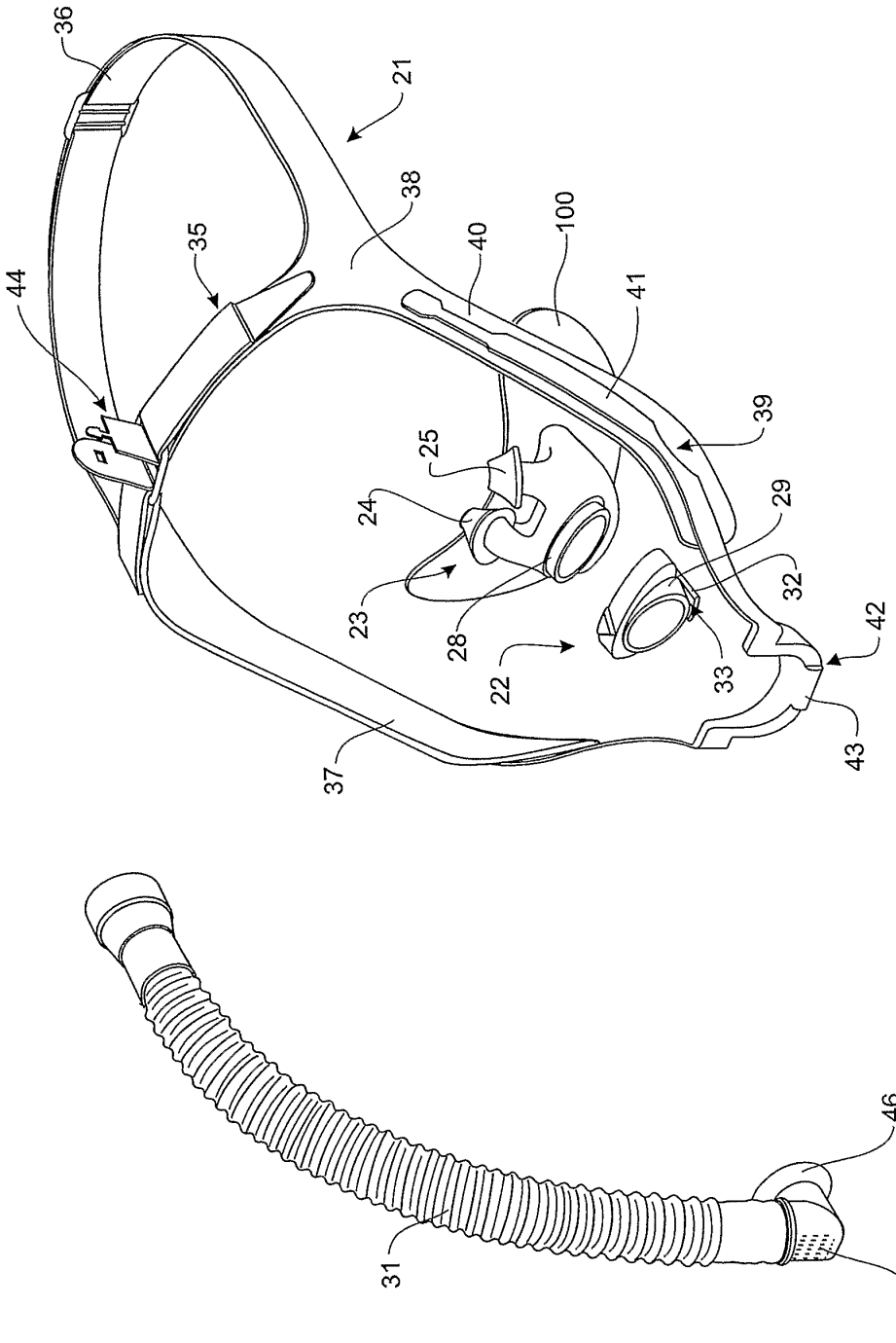

FIGURE 10

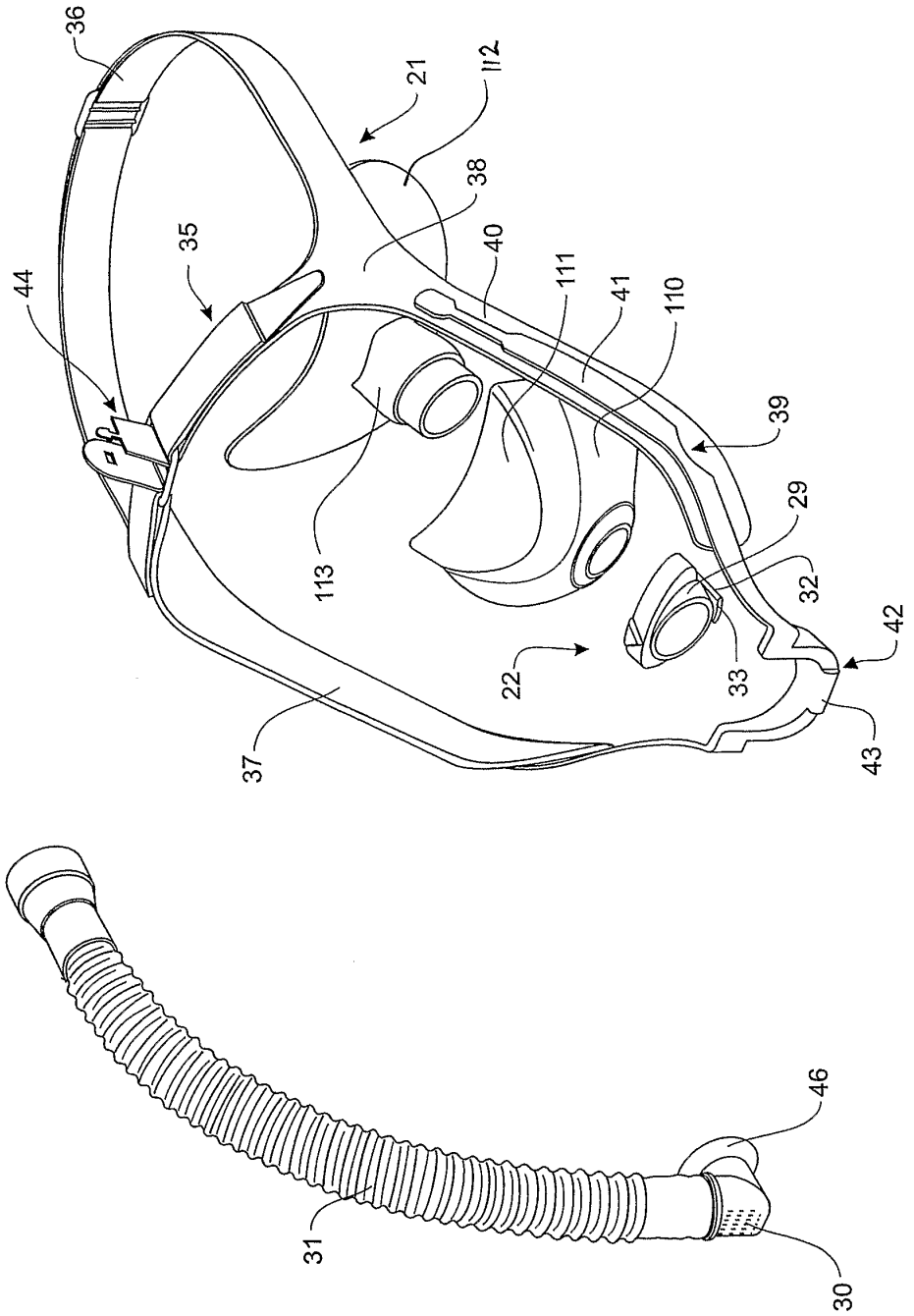

FIGURE 11

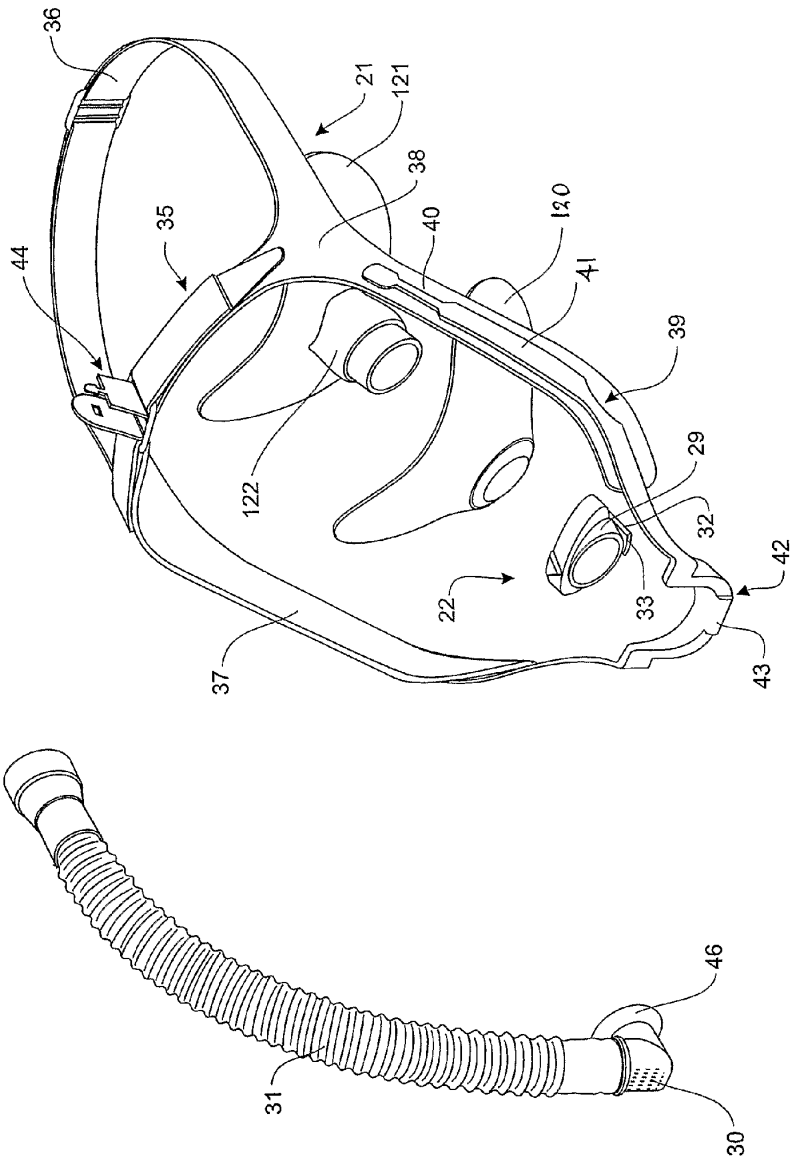

FIGURE 12

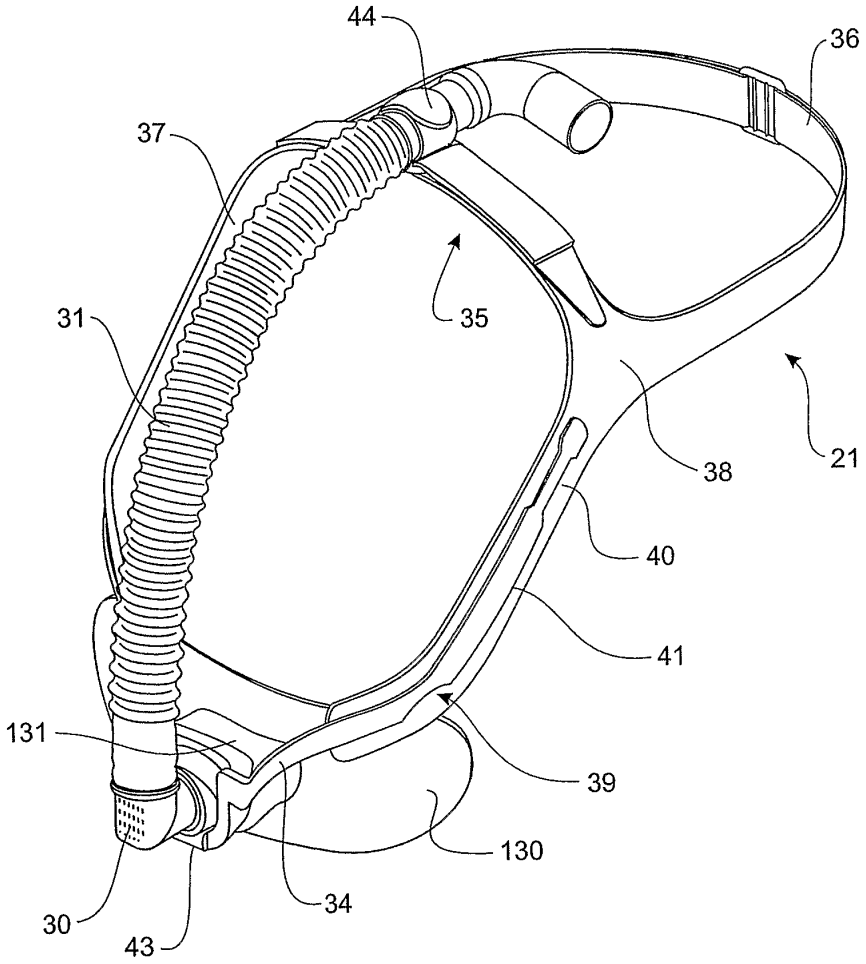

FIGURE 13

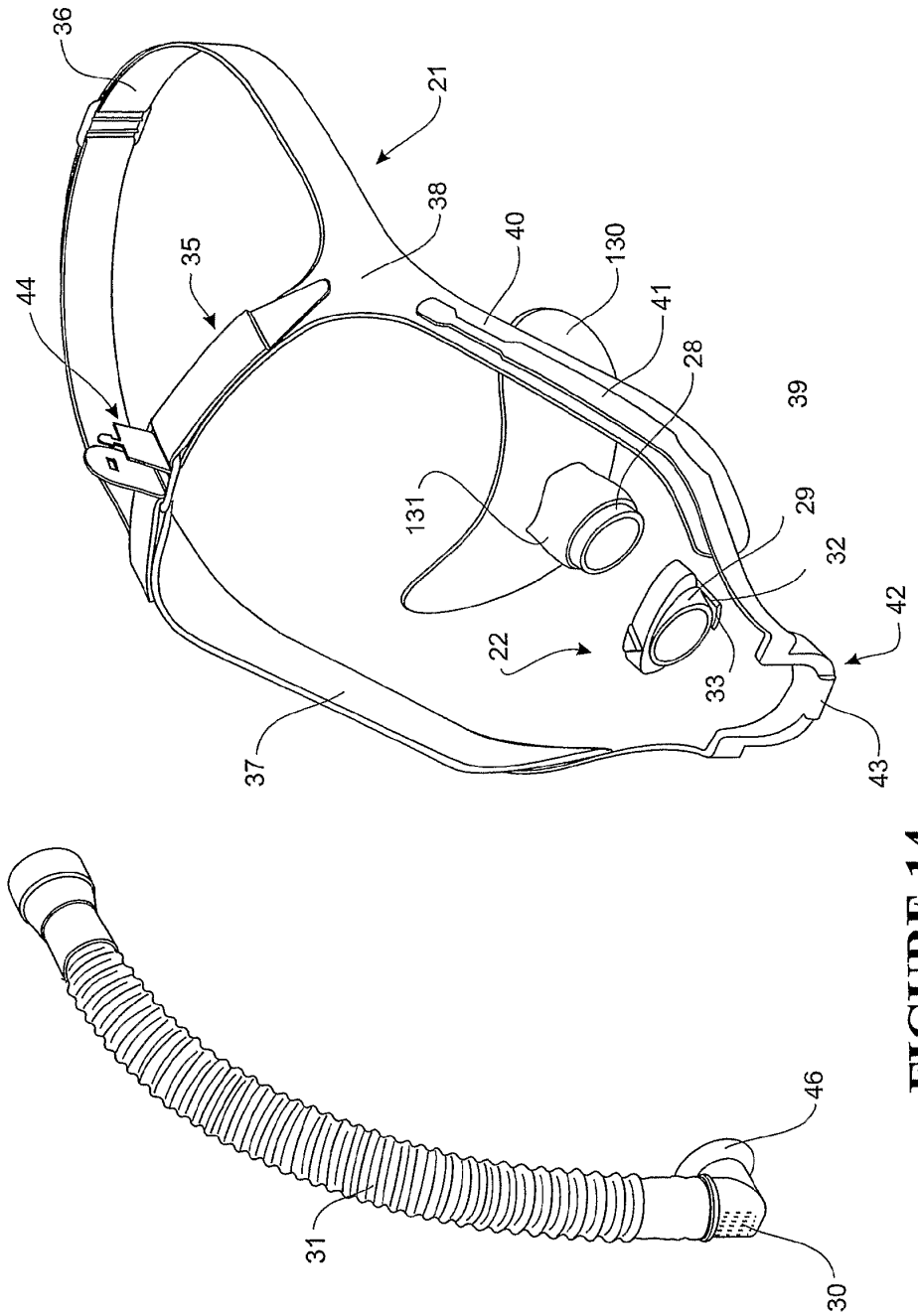

FIGURE 14

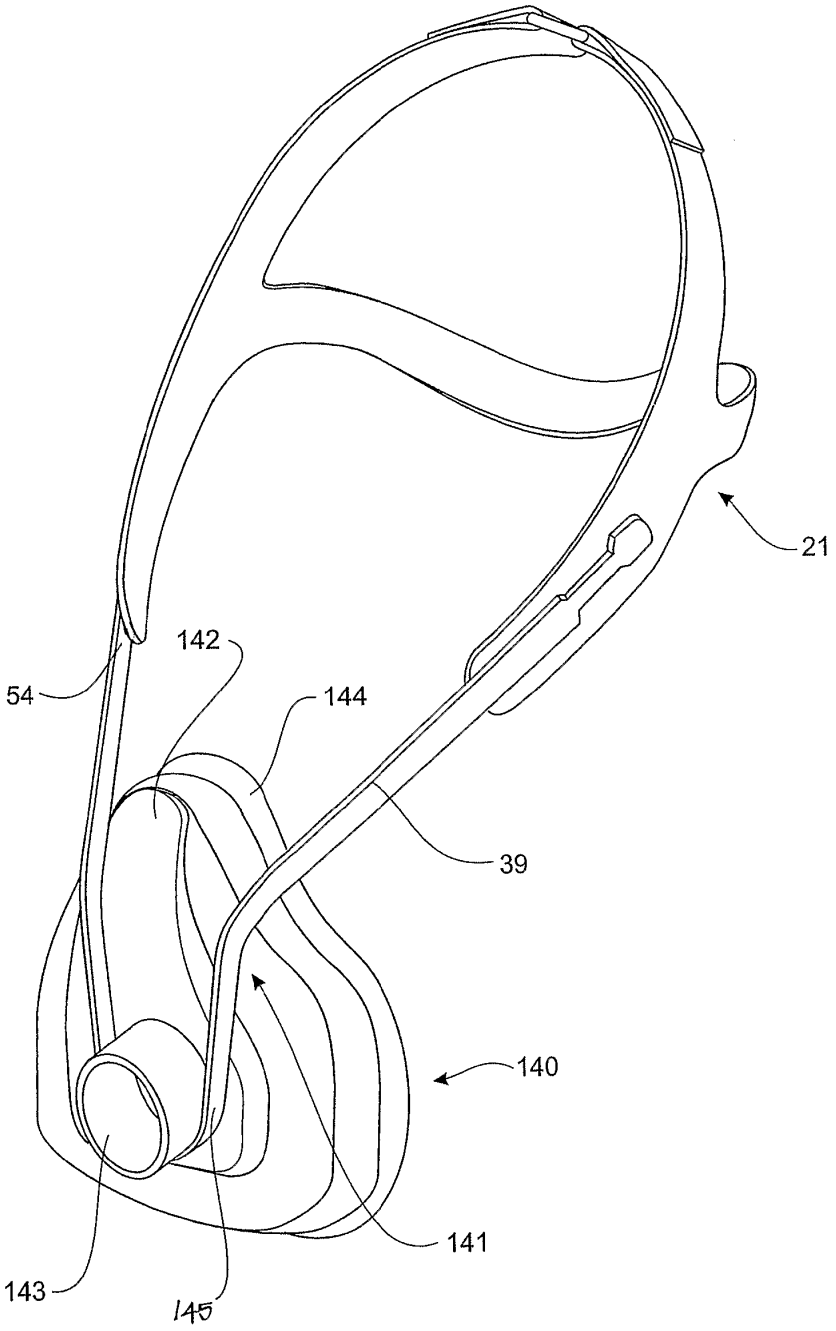

FIGURE 15

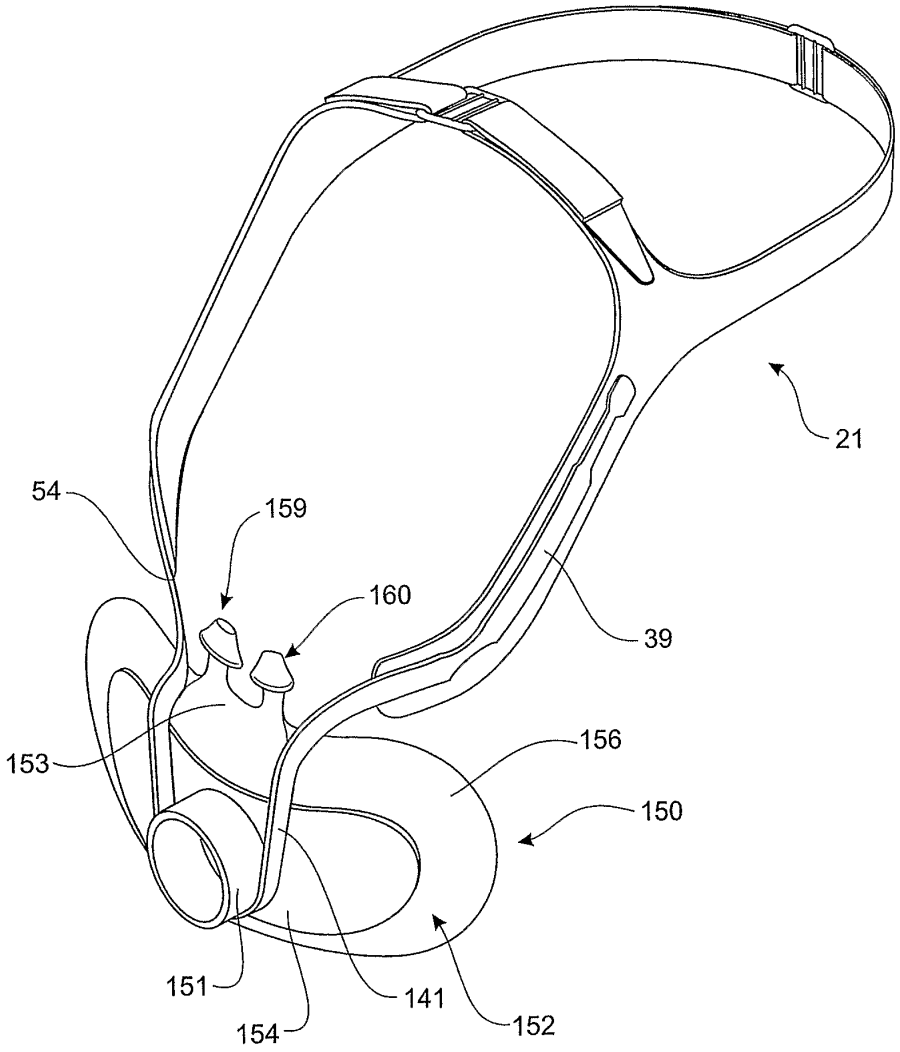

FIGURE 16

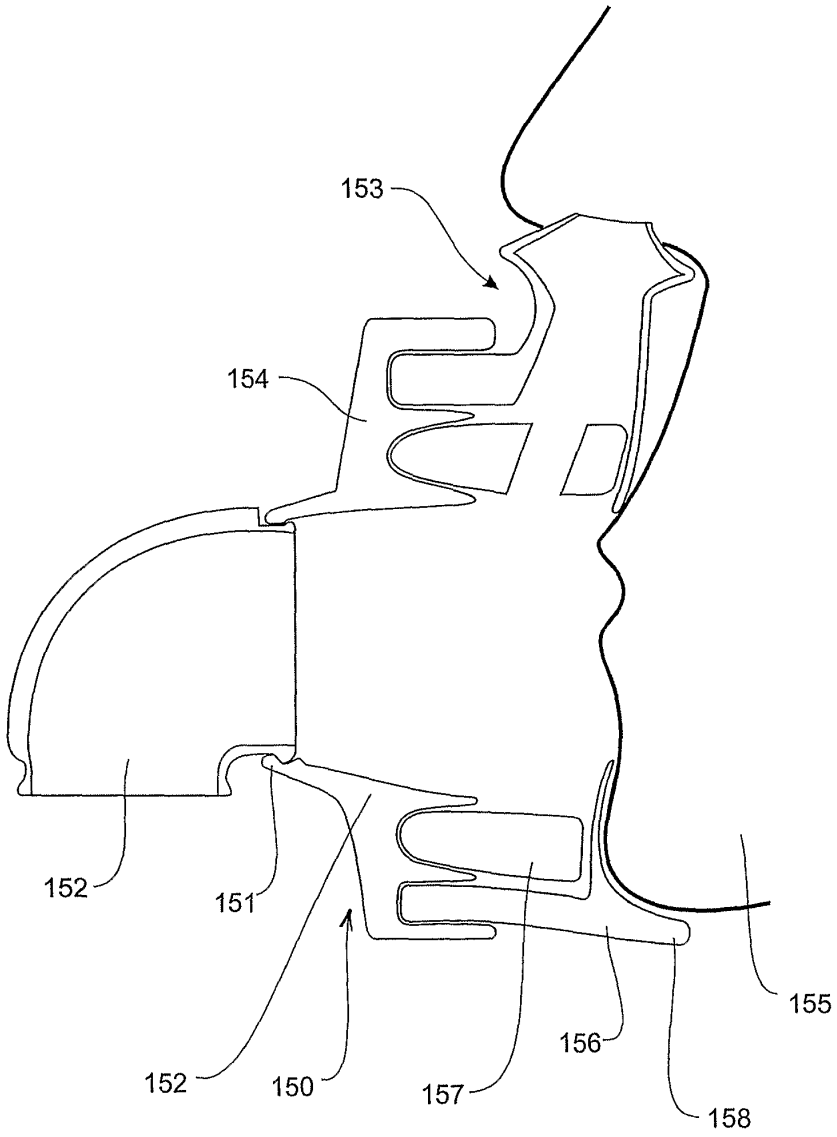

FIGURE 17

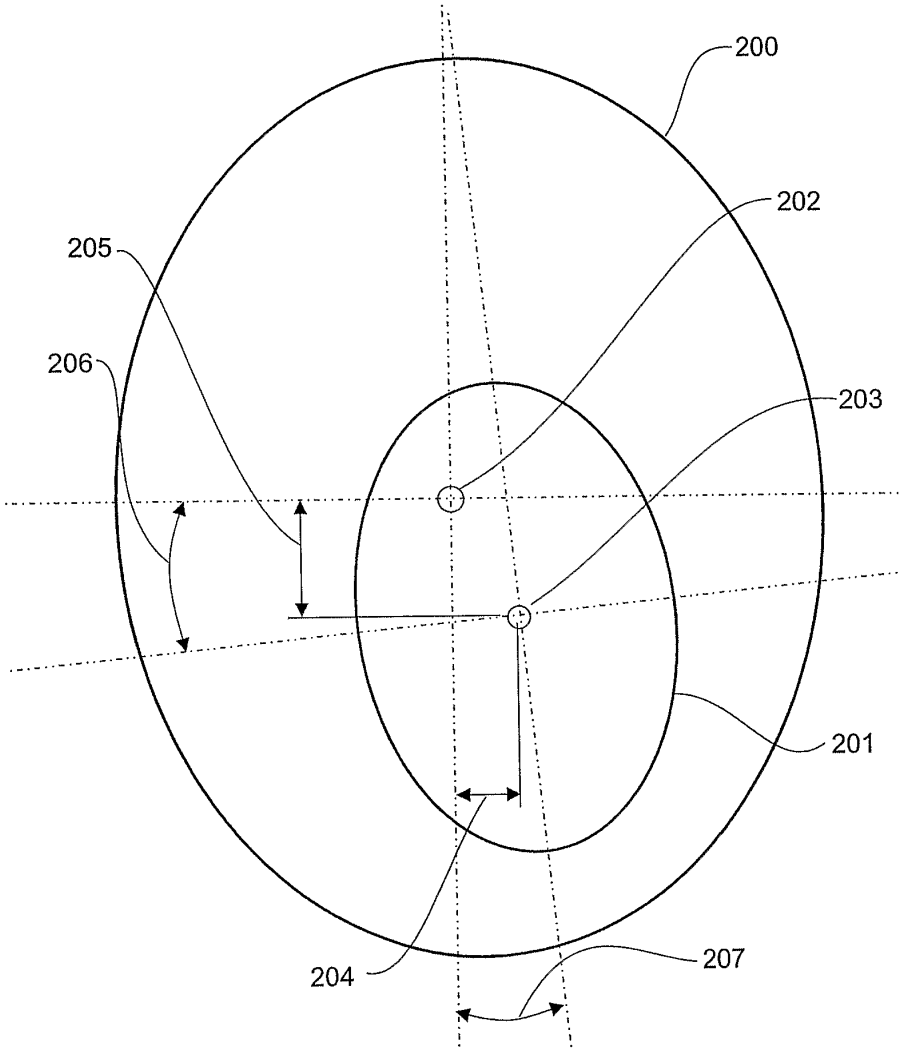

FIGURE 18

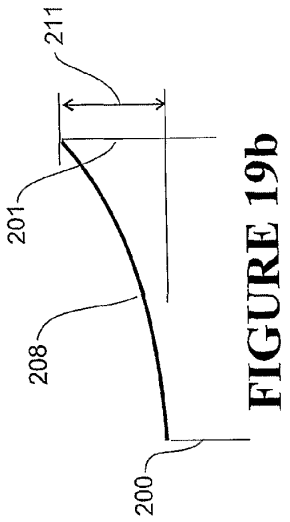

FIGURE 19b

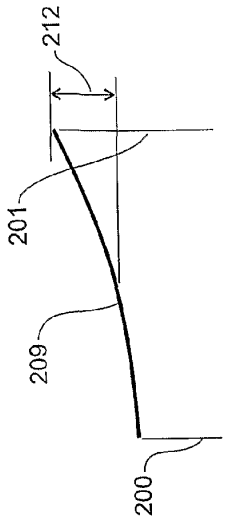

FIGURE 19c

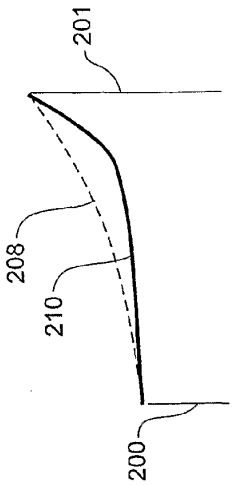

FIGURE 19d

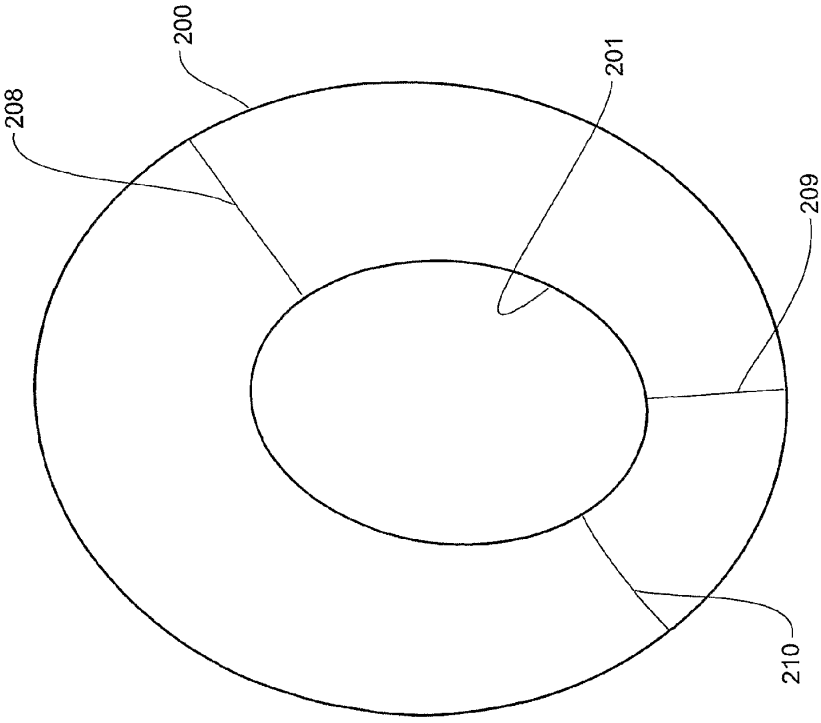

FIGURE 19a

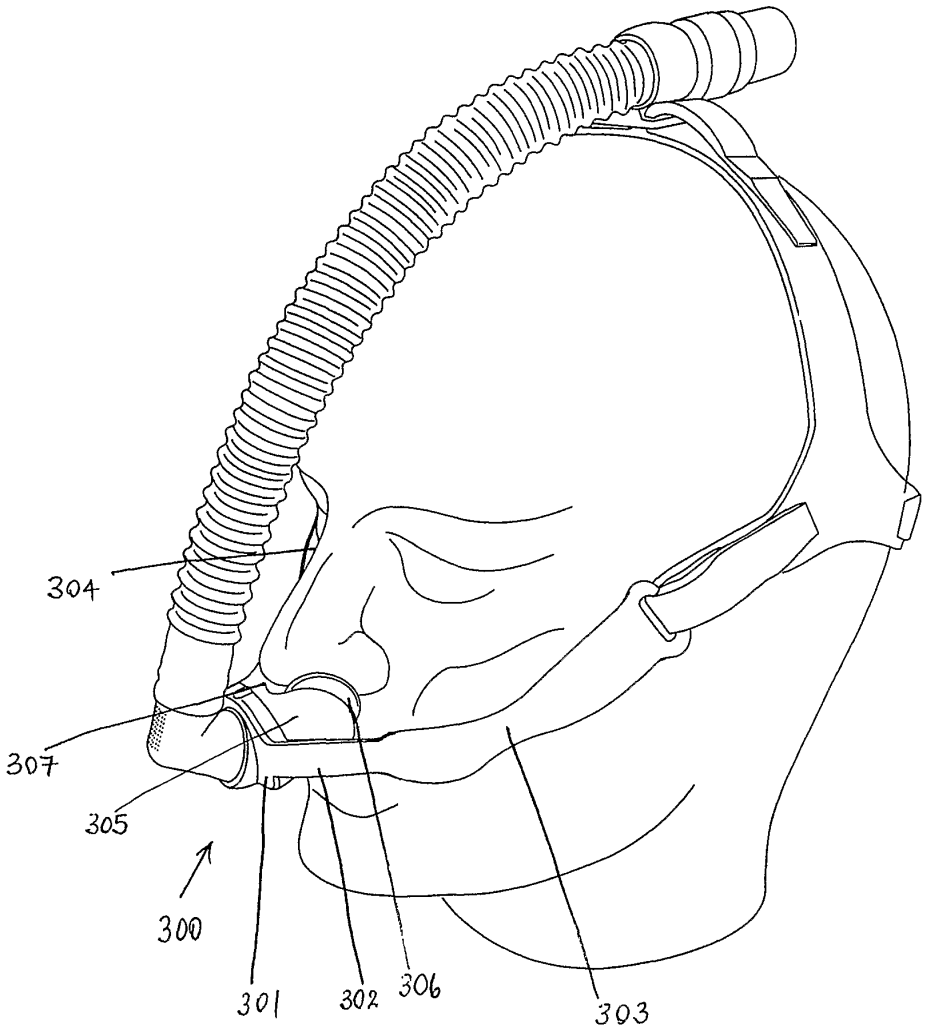

FIGURE 20

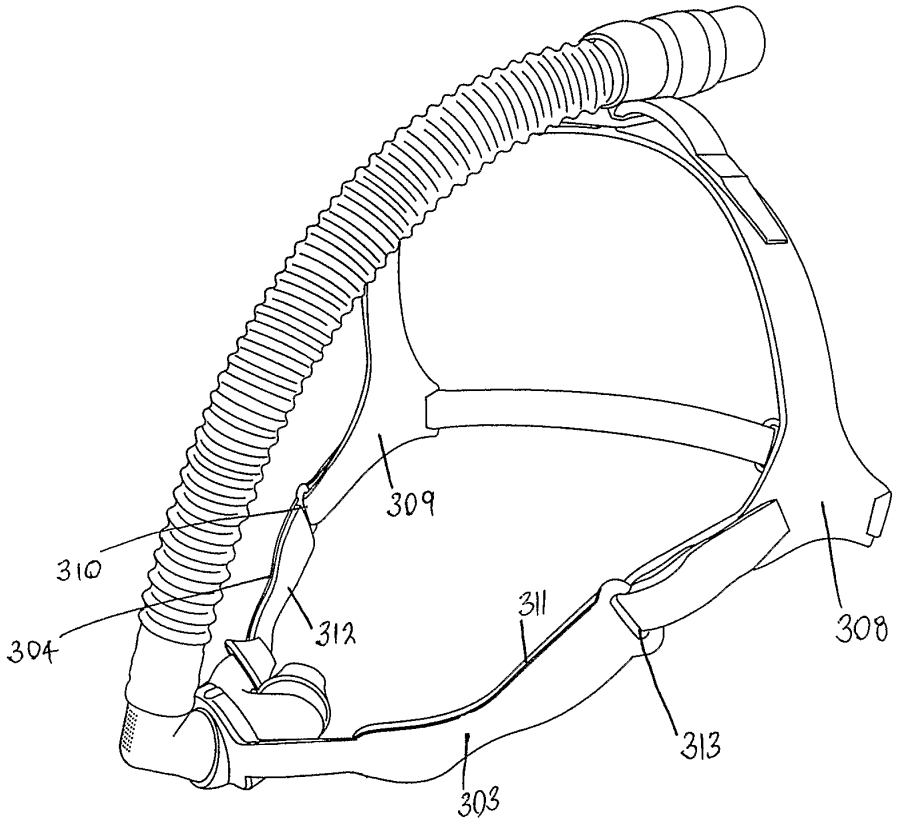

FIGURE 21

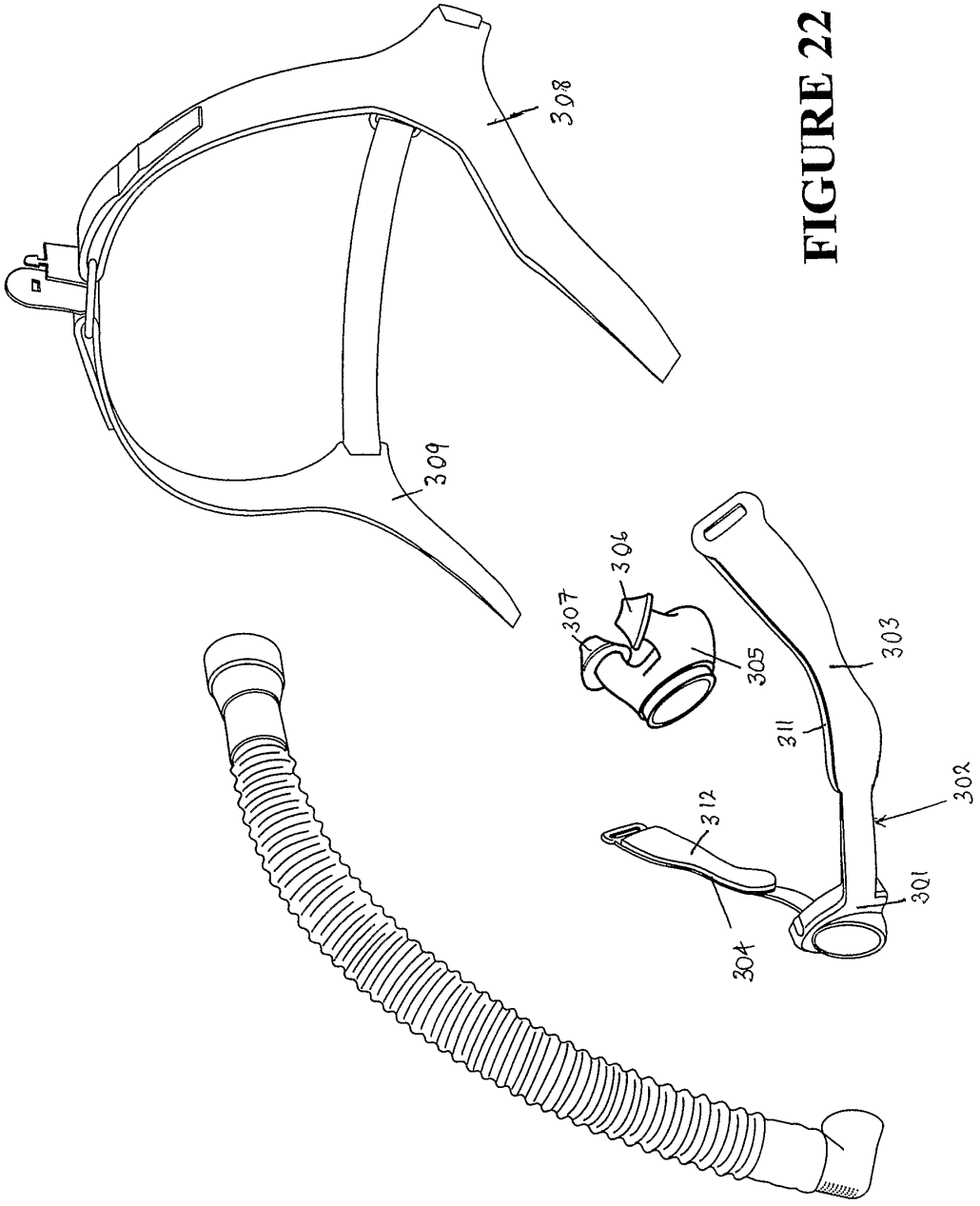

FIGURE 22

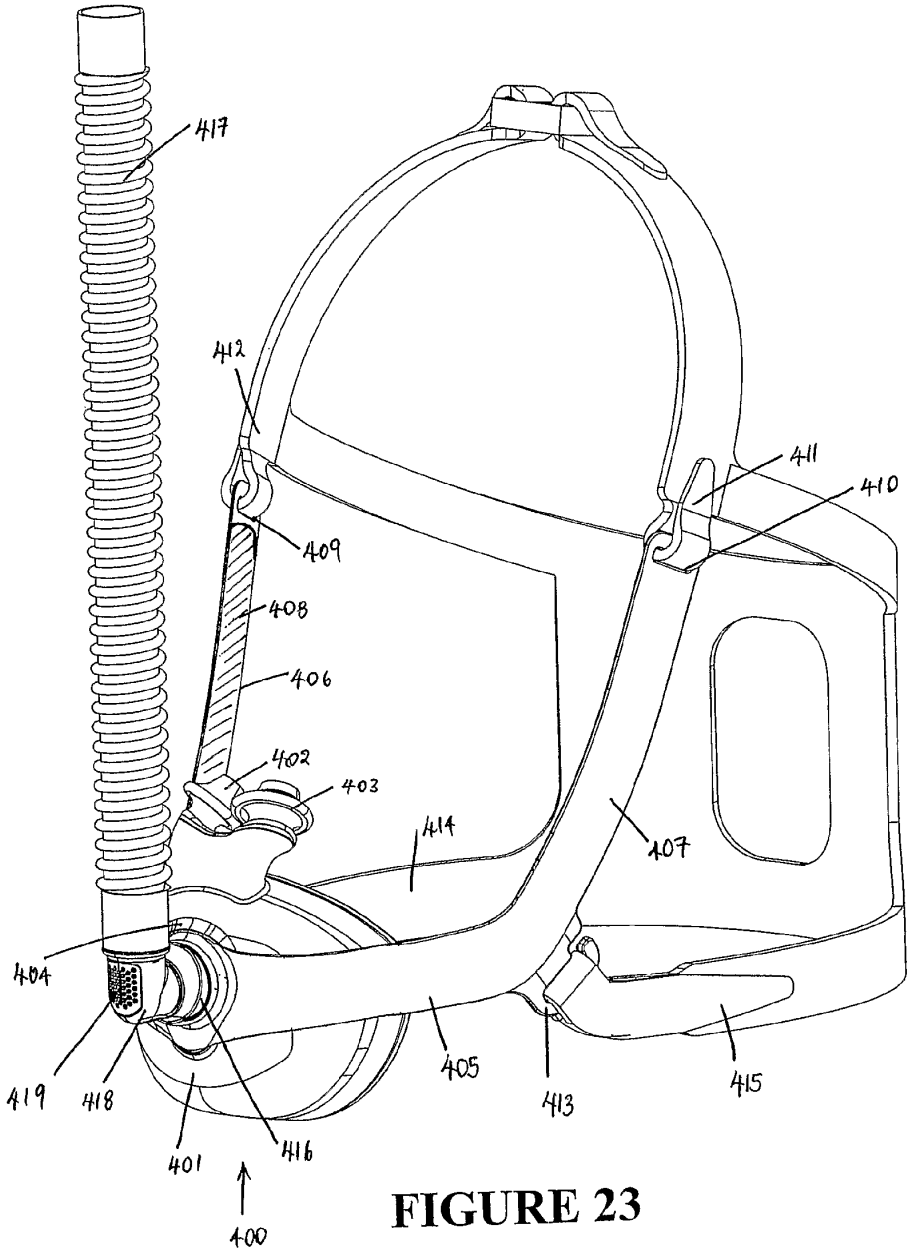
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FIGURE 23

BREATHING ASSISTANCE APPARATUS

This application is a National Phase filing of PCT/NZ2007/000185, having an International filing date of Jul. 13, 2007, which disclosure is herein incorporated by reference.

BACKGROUND OF THE INVENTION

1. Technical Field

The present invention relates to apparatus for treating sleep apnoea. More specifically, the present invention provides a nasal interface for the supply of respiratory gases, but most particularly positive pressure gases.

2. Summary of the Prior Art

In the art of respiration devices, a variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face are well known. Masks that provide gas at positive pressure within the mask for consumption by the user are also well known. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

Obstructive Sleep Apnoea (OSA) is a sleep disorder that affects up to at least 5% of the population in which muscles that normally hold the airway open relax and ultimately collapse, sealing the airway. The sleep pattern of an OSA sufferer is characterised by repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep. Often the sufferer is unaware of this pattern occurring. Sufferers of OSA usually experience daytime drowsiness and irritability due to a lack of good continuous sleep.

In an effort to treat OSA sufferers, a technique known as Continuous Positive Airway Pressure (CPAP) was devised. A CPAP device consists of a gases supply (or blower) with a conduit connected to supply pressurised gases to a patient, usually through a nasal mask. The pressurised air supplied to the patient effectively assists the muscles to keep the patient's airway open, eliminating the typical OSA sleep pattern.

The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4 to 20 cm H_2O. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery hose to a nose, full face, nose and mouth, or oral mask that is sealingly engaged to a patient's face, preferably by means of a harness or other headgear. An exhaust port is usually also provided in the delivery tube proximate to the mask or on the mask itself. More sophisticated forms of positive airway pressure devices, such as bi-level devices and auto-titrating devices, are described in U.S. Pat. No. 5,148,802 of Respironics, Inc. and U.S. Pat. No. 5,245,995 of Rescare Limited, respectively.

One requisite of respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. A common complaint of a user of CPAP therapy is pressure sores caused by the mask about the nose and face and in particular in the nasal bridge region of the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

U.S. Pat. No. 5,477,852 of Airways Ltd, Inc. discloses a nasal positive airway pressure device that has a pair of nasal members each having a cannula tip to be inserted into the nares of the patient. Each cannula is tapered from a substantially circular cross section outside the patient's nostril to a substantially oval cross section at the tip inserted into the nostril. An inflatable cuff surrounds each cannula with the interior space of the cuff communicating with the lumen of the cannula through at least one aperture in the sidewall of the cannula. The nasal members are connected to one or more flexible hoses that, in turn, are connected to a source of positive air pressure. In use, positive air pressure is supplied to each cannula tip through the air hoses and nasal members. The positive air pressure inflates the cuffs to hold the nasal members in place and to effect treatment. The nasal device of U.S. Pat. No. 5,477,852 is attached to headgear that is located about a patient's head. This headgear could be considered by many patients as cumbersome and uncomfortable.

Conventional nasal masks used for administrating CPAP treatment are also considered uncomfortable and cumbersome, and prior art nasal masks can be noisy due to air leaks. These disadvantages in many cases are a formidable obstacle to patient acceptance of such treatment. Therefore, a substantial number of patients either cannot tolerate treatment or choose to forego treatment. It is believed a number of such patients might benefit from a nasal positive airway pressure apparatus that is more convenient to use and comfortable to wear, thereby resulting in increased treatment compliance.

Innomed Technologies, Inc. manufactures a nasal cannula device called the NASALAIRE™. In this device air or oxygen travels down a wide bore conduit to nasal cannula. The NASALAIRE™ creates a physical seal between the nares and itself, and relies on the absence of leaks around the cannula and the nares to deliver pressure supplied by a continuous positive airway pressure (CPAP) blower to the airway of the wearer.

U.S. Pat. No. 6,119,694 of Respironics Georgia, Inc discloses a nasal mask having a nare seal and lateral support members to support the mask.

WO2004/073778 of ResMed Limited discloses anasal mask including a frame where headgear is provided with rigid sections that extend to the nasal mask.

WO04/041341 of ResMed Limited discloses headgear for a patient mask that includes a sewn on rigid section to the back area of headgear straps to provide rigidity to the straps.

U.S. Pat. No. 6,907,882 of ResMed Limited discloses a nasal mask and headgear that is attachable to the frame of the nasal mask. The headgear straps have rigid sections integral with the releasable connectors that attach the headgear to the mask.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface that goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

In a first aspect the present invention consists in headgear for use with a respiratory mask comprising:

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask, said attachment capable of receiving said mask.

In a second aspect the present invention consists in a breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask having a base and body, said body having two flexible nasal pillows that in use rest in a substantially sealed manner against said user's nares,

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed below said user's nose, said attachment capable of receiving said mask.

In a third aspect the present invention consists in a breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask comprising a body and a cushion, said cushion substantially forming a seal with said patient's airways,

headgear comprising substantially flexible, soft straps and a substantially continuous curved elongate member to which said mask is attached, said elongate member extending over said user's cheeks, and

wherein said mask has an inlet extension tube and said curved elongate member is attached or rests beneath said inlet extension tube, anchoring said mask to said user's face in use.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE FIGURES

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

FIG. **1** is a block diagram of a humidified continuous positive airway pressure system as might be used in conjunction with the nasal mask of the present invention.

FIG. **2** is a perspective view of a first form of a patient interface that is nasal mask and headgear of the present invention.

FIG. **3** is an exploded view of the nasal mask and headgear of FIG. **2**.

FIG. **4** is a side view of a mask base of the nasal mask and headgear of FIG. **2**.

FIG. **5** is a perspective end view of the mask base of FIG. **4**.

FIG. **6** is an end view of a body of the nasal mask and headgear of FIG. **2**, particularly showing two nasal pillows.

FIG. **7** is a perspective view of the body of FIG. **6**.

FIG. **8** is a perspective view of a nasal mask of the first form of the present invention but having alternative headgear that includes additional rigid extensions.

FIG. **9** is perspective view of a second form of a patient interface and headgear of the present invention.

FIG. **10** is an exploded view of the patient interface and headgear of FIG. **9**.

FIG. **11** is an exploded view of a third form of a patient interface and headgear of the present invention.

FIG. **12** is an exploded view of a fourth form of a patient interface and headgear of the present invention.

FIG. **13** is a perspective view of a fifth form of a patient interface and headgear of the present invention.

FIG. **14** is an exploded view of the patient interface and headgear of FIG. **13**.

FIG. **15** is a perspective view of a sixth form of a patient interface and headgear of the present invention.

FIG. **16** is a perspective view of a seventh form of a patient interface and headgear of the present invention.

FIG. **17** is a cross-sectional view of the patient interface of FIG. **16**.

FIG. **18** is a front view of a nasal pillow of FIG. **6**.

FIG. **19***a* is a front view of the nasal pillows of FIG. **6**.

FIGS. **19***b* to **19***d* are graphs of the gradients of various nasal pillow connecting surfaces.

FIG. **20** is a perspective view of an eighth form of a patient interface and headgear of the present invention.

FIG. **21** is a perspective view of the interface and headgear of FIG. **20** showing inner pads on the arms of the headgear.

FIG. **22** is an exploded view of the interface and headgear of FIG. **20**.

FIG. **23** is a perspective view of a ninth form of a patient interface and headgear the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

The breathing assistance apparatus of the present invention including masks and headgear as described in the preferred embodiments of this invention can be used in respiratory care generally or with a ventilator. It is described below with reference to use in a humidified CPAP system.

A humidified Continuous Positive Airway Pressure (CPAP) system is shown in FIG. **1**. A patient **1** is receiving humidified and pressurised gases through a patient interface **2** connected to a humidified gases transportation pathway or inspiratory conduit **3**. Alternative delivery systems may also be used such as, VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. A nasal mask **2** is illustrated in FIG. **7** but other masks such as oral, full face or nasal cannula may be used.

An inspiratory conduit **3** is connected to an outlet **4** of a humidification chamber **5** that contains a volume of water **6**. The inspiratory conduit **3** may contain heating means or heater wires (not shown) that heat the walls of the conduit to reduce condensation of humidified gases within the conduit **3**.

The humidification chamber **5** is preferably formed from a plastics material and preferably has a highly heat conductive base (for example an aluminium base) that is in direct contact with a heater plate **7** of humidifier **8**. The humidifier **8** is provided with control means or an electronic controller **9** that may comprise a microprocessor based controller executing computer software commands stored in associated memory.

The controller **9** preferably receives input from sources such as user input means or a dial **10** through which a user of the device may, for example, set a predetermined required

value (preset value) of humidity or temperature of the gases supplied to patient **1**. The controller **9** may also receive input from other sources, for example temperature and/or flow velocity sensors **11**, **12**, through a connector **13** and a heater plate temperature sensor **14**. In response to the user set humidity or temperature value input via the dial **10** and the other inputs, the controller **9** determines when (or to what level) to energise the heater plate **7** to heat the water **6** within the humidification chamber **5**. As the volume of the water **6** within the humidification chamber **5** is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber **5** outlet **4** with the flow of gases (for example air) provided from a gases supply means or blower **15** that enters the chamber **5** through an inlet **16**. Exhaled gases from the patient's mouth are passed directly to the ambient surroundings in FIG. **1**.

The blower **15** is provided with variable pressure regulating means or variable speed fan **21** that draws air or other gases through a blower inlet **17**. The speed of the variable speed fan **21** is controlled by an electronic controller **18** (or alternatively the function of the controller **18** may be carried out by the controller **9**) in response to inputs from the controller **9** and a user set predetermined required value (preset value) of pressure or the fan speed via dial **19**.

FIGS. **2** and **3** show a first embodiment of a patient interface of the present invention. This patient interface is a nasal mask **2**. The nasal mask **2** is comprised of a mask base **22** and body **23**. The body **23** is substantially tubular with two nasal pillows **24**, **25** extending from it. The nasal pillows **24**, **25** are preferably frustoconical in shape and in use rest against a patient's nares, to substantially seal the patient's nares. The body **23** has an external lip **28** that frictionally fits in a channel in the mask base **22**.

The body **23** and nasal pillows **24**, **25** of the nasal mask of the present invention are shown in further detail in FIGS. **6** and **7**. The body and pillows are preferably integrally moulded in a substantially flexible plastics material. In the preferred form this material is silicone, but other appropriate materials, such as, rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used.

The nasal pillows **24**, **25** are preferably an elliptical cone and as such are tubular and allow for a passage of gases to flow from the tubing **3** and through the mask body **23**. The pillows **24**, **25** are preferably angled toward one another and each have a preferably elliptical outlet **26**, **27** that may be slightly offset from the centre of each pillow **24**, **25**, as shown in FIG. **6**.

FIGS. **18** and **19***a* show a nasal pillow **24** with an offset outlet in more detail. The pillow **24** has an outer profile **200** and inner profile **201** with respective centre points **202**, **203**. The inner profile **201** (outlet of the nasal pillow **24**) is offset inward, by a horizontal spacing **204** and vertical spacing **205**. Meaning the outlet **201** of the nasal pillow is offset horizontally **204** towards the middle of the nose and vertically **205** towards the user's upper lip. Offsetting the outlet **201** downwards in this manner allows the outlet to be inserted into a user's nostril without the outer profile **200** pushing the user's upper lip. Offsetting the outlet **201** inwards allows the pillow to better seal on the septum of the user's nose in use.

The outlet **201** may also be angled compared to the outer profile **200**. For example in FIG. **18**, there is a horizontal angle difference between the outer profile **200** and outlet **201** shown as **206**. A similar vertical angle difference between the outer profile **200** and outlet **201** is shown as **207**.

With the outer profile and inner profile having different sections or offsets allows the gradient of the connecting surface between the profiles to be changeable. This is shown in the graphs of FIGS. **19***b*, **19***c* and **19***d*. The connecting surface between the inner **201** and outer **200** profiles can have differing gradients, **208**, **209**, **210**. The different gradients **208**, **209**, **210** of the connecting surface are possible due to the difference in offset difference **211**, **212** (horizontal, vertical or angled) between the inner **201** and outer **200** profiles.

There may also be a difference in the rate of change of the gradient (as illustrated in the difference between **208** and **210**). This allows easier insertion of the pillow **24** into a user's nostrils due to more lead in and better sealing that may be achieved due to more ergonomic contouring of the connecting surface that contacts the user's nostril.

Referring back to FIG. **7**, the external lip **28** on the mask body **23** is an area of reduced circumference around the tubular part of the body **23**. A projection **47** may be provided on the lip **28** that fits with a corresponding recess or channel (discussed below) on the mask base **22** to ensure correct assembly of the nasal mask.

The mask base **22** is shown in further detail in FIGS. **4** and **5**. The mask base **22** is a ring or sleeve type attachment. The base **22** is preferably made from a substantially hard (rigid) plastics material, such as polypropylene, polycarbonate or acetyl. However, other appropriate materials may be used. The base **22** has an internal circumferential recessed area or channel **45** on one side and a semi-tubular projection **29** on its other side. When assembling the mask body **23** to the mask base **22** the channel **45** receives the lip **28**. These parts are maintained together by friction fit, however other types of fitting may be provided for, such as a snap or bump fitted part or the body may be over moulded to a clip that causes the fitting to the mask body **23**. In this form the friction fitting of the lip **28** to the recessed area **45** is assisted by elongate projections **49** extending along the central part **50** of the mask base **22**. The projection **47** on the mask body **23** allows for correct fitting or keying of the mask base to the mask body, such that when the lip **28** is fitted into the recessed area **45**, the projection **47** enters the recess **48** formed in the mask base **22**.

The semi-tubular projection **29** is curved in this embodiment such that a ball jointed connector end **46** such that a connector **30** can be fitted into it. The projection **29** forms a socket for the connector end **46** and the connector end can swivel within the socket. The connector **30** is attached to a tube **31** to allow for gases to be passed to the nasal mask **2**. The tubing **31** may be attached to inspiratory conduit **3** or the tubing **31** may simply be the inspiratory conduit **3**.

In alternative embodiments the projection **29** may not be semi-circular but the inner surface of the base **22** may be curved and form a socket for receiving the connector end **46**.

The base **22** has an extension or partial lip **32** extending beneath the semi-tubular projection (socket) **29**. A slot **33** is created between the socket **29** and extension **32**. The extension and slot is used to fit the mask base **22** to the headgear **21**. In this embodiment the extension **32** is substantially curved to follow the shaped of the projection **29**. However, in other forms the extension may be substantially straight or otherwise shaped.

In use, the nasal mask is assembled with headgear **21**. The headgear **21** in the preferred form is comprised of headgear straps **35**, **36**, **37**, **38** and a substantially curved and elongate member **34**. The member **34** is curved and substantially rigid, or at least more rigid than the headgear straps.

The headgear straps **35**, **36**, **37**, **38** are preferably made from a composite foam layered material, such as Breathoprene™. The headgear **21** preferably includes a first strap **35** and a second strap **36**. The first strap **35** extends in use over the forehead or top front area of a patient's head. The second strap **36** extends around the back of the patient's head. The head-

gear **21** also has side straps **37**, **38** that in use extend down the cheeks of a patient and the ends of the straps terminate in the upper lip area of the patient in use.

Referring to FIG. **2**, the curved and elongate member **34** is comprised of a central section **42** and contoured side arms **41**, **54**. A substantial length of each of the side arms **41**, **54** overlaps and is attached to the side straps **37**, **38**. However, the side straps **37**, **38** only extend partially along the length of the side arms **41**, **54** so as to terminate beneath the cheek or near the upper lip region. As the side straps **37**, **38** are made from a soft foam type material they provide a comfortable fitting of the headgear and curved member **34**, while the substantially rigid side arms **41**, **54** provide rigidity and stability to the headgear **21** and nasal mask **2**. The attachment between the side straps and rigid extension side arms may be made by gluing, sewing or other appropriate fastening.

Preferably the side arms of the curved member **34** are integrally moulded with the central section **42**. The curved member **34** is preferably three dimensionally moulded to a shape to substantially match the cheek contours of a human. The side arms **41**, **54** are preferably of thinner width (cross-section) than the central section **42**. As the side arms **41**, **54** are moulded of a plastics material to be substantially thin they are capable of being bent or adjusted to allow for better and more comfortable fit to a patient. The side arms **41**, **54** may also include weakened or narrow areas **39** to allow for additional bending, moulding or twisting of the arms **41**, **54** to better fit the headgear to individual patients. For example, in the embodiment shown in FIGS. **2** and **3**, the narrowed area **39** corresponds to the cheek bone area of a patient and allows for the side arms **41**, **54** to easier bend or twist to fit the contours of the patient's face.

In alternative embodiments the side arms may have weakened areas that are narrower in cross-section to that of the remainder of the side arms. A narrower cross-section area would also provide a weakened area that may be easily manipulated.

In alternative embodiments of the present invention the side straps of the headgear may not extend under and along the length of the curved member but be attached to the distal ends of the straps. This attachment may be by hook and loop material, as is known in the art, or by other attachment methods as known in the art. In this form, the arms of the curved member may have padding underneath them or no padding at all.

Referring to FIG. **3**, the curved elongate member has a central section **42** that in an assembled form supports the mask base and body such that the pillows **24**, **25** rest against the patient's nares. The central section **42** is a half circle that is integrally moulded with the side arms **41**, **54**. The central section **42** has a raised area **43** on its exterior, at the apex of the half circle. The raised area **43** is shaped to receive the mask base **22**. To assemble, a patient merely needs to slide the mask base **22** into the central section **42** such that the raised area **43** fits into the slot **33** on the mask base **22**.

The side arms **41**, **54** of the curved member **34** preferably have varying cross-sectional thickness. The ends of the arms **41**, **54** attached to the central section **42** are thicker over the most curved parts **55**, **56** of the arms, whereas the straighter parts of the arms **57**, **58** have a narrow cross-section. Therefore, the thicker ends **55**, **56** hold their shape better.

In alternative embodiments, the mask base **22** may be formed integrally with the curved member **34**. Therefore, the central section and base would be one and would not be able to be separated from one another.

An example of this is shown in FIGS. **20** to **22**, the eighth embodiment of the patient interface and headgear **300**. Here, the mask base **301** and the curved elongate member **302** are integrally formed, for example, by moulding or the like. The elongate member comprises arms **303**, **304** similar to that described above. Also the mask body **305** has integral nasal pillows **306**, **307** similar to that described above in relation to FIG. **2**.

As can be seen in FIGS. **21** and **22** in this eighth embodiment the headgear straps **308**, **309** do not extend down the arms **303**, **304** as with other embodiments. In this embodiment the headgear straps **308**, **309** attach through recesses **310**, **313** at the end of the arms **303**, **304** extending along the arms are inner pads **311**, **312** that rest against the patient's cheekbones in use and provide comfort to the patient's face. The pads **311**, **312** only extend up to near the attachment recesses **309**, **310**. The pads are preferably made from a foam type material, such as the laminated material that the headgear straps are made from. The pads **311**, **312** preferably do not extend beyond the edges of the arms **303**, **304**.

Referring back to FIGS. **2** and **3**, alternatively, the curved member **34** may be formed as two separate pieces. That is, the central section **42** may be formed as two parts with a central split seam, the two left and right halves joined in use. The two left and right parts could either be joined along a seam as described above, with the base **22** slotting into the slot **33** as described above, or alternatively, each of the two left and right arms may be attached one to each side of the base **22**.

Where a "substantially continuous elongate member" or "curved member" is referred to in this specification, it refers to any of the options for the curved member **34** outlined above.

The side arms **41**, **54** may also include a loop **40** or detached section. This is where a section of the side arms **41** is not attached to the strap **38**, **37** lying underneath. Thus the detached section **40** of the side arms forms a loop to which a tubing attachment **44** (such as that shown attached to another strap in FIGS. **2** and **3**) may be looped to the side arms **41**, **54** and the tubing **31** attached to either of the side arms.

The connector **30** in the preferred form is a ball and socket jointed connector to allow for the tubing **31** to swivel in the mask base **22**. The tubing **31** may be attached to any of the headgear straps. However, a tube attachment **44** is shown where the tubing is attached by fasteners, such as hook and loop fastener, to the first strap **35**. In other embodiments the tubing **31** may be attached to either the side straps **37**, **38** or merely allowed to fall freely from the nasal mask **2**.

Although a ball and socket joint, as described above, between the mask base **22** and tubing **31** is preferred other connections may be utilised, such as a flexible piece of silicone, or other appropriate connection. The connection between the base and tubing must be able to be flexed or rotated to allow for the tubing to be moved without causing the dislodgement of the nasal mask **2** from the user's nares.

The mask body **23** may be provided with nasal pillows of various different sizes, such that user's may remove an existing mask body and simply attach a different sized body to the mask base **22**.

Alternative headgear may be used with the patient interface of the present invention. In particular, alternative headgear is shown in use with the first form of the patient interface (of FIG. **2**) in FIG. **8**. Here the headgear may include an additional strap **53** extending from the cheek region of the side straps **41** and extending behind the user's head. This lower additional strap **53** may also include substantially rigid arms **51** similar to the arms **41** described above. Any number of connecting straps **52** may also be provided between the upper strap **36** and lower strap **53**. Again, the arms **51** would provide stability and rigidity to the additional strap **53**.

In the embodiment described above, when the patient interface of the first form is in use, the user's face causes the mask base **22** and body **23** to clip with the curved member **34**. This is due to the angle of the curved member **34** and fixing of the mask base **22** and body **23** to the curved member **34**.

Further, in all forms, the curved member **34** transfers the load of the patient interface away from the user's nose and to the cheek regions of the user.

A second form of the patient interface and headgear of the present invention is shown in FIGS. **9** and **10**. In this embodiment a mouthpiece **100** is attached to the substantially tubular mask body **23** substantially below the nasal pillows **24**, **25**. The mouthpiece **100** is preferably a flap that is fittable within the patient's mouth. A gases pathway extends through the mask body **23** and through the centre of the mouthpiece **100**, such that in use a patient or user is supplied with gases via the nasal pillows **24**, **25** and the mouthpiece **100**. The flap **100** is preferably made from a silicone plastics material but other appropriate materials such as rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used. The flap **100** is preferably integrally moulded with the mask body **23** and nasal pillows **24**, **25**. In use the flap **100** sits within the user's mouth between the user's teeth and lips.

In this second form the headgear and particularly the curved member **34** is substantially the same as that described in relation to the first embodiment.

A third form of the patient interface and headgear of the present invention is shown in FIG. **11**. In this embodiment a mouthpiece as well as a nose blocking device is attachable to the mask base **22**. The mouthpiece **110** and nose blocking device **111** are preferably integrally formed. The mouthpiece **110** has an inner vestibular shield **112** that is similar to the flap **100** described above. Therefore the vestibular shield **112** in use sits within the patient's mouth between the patient's teeth and lips and provides an at least partial seal between the user and the shield **112**.

A tubular extension **113** extends through the mouthpiece **110** to the mask base **22** from the vestibular shield **112**. The extension allows for gases to be passed to the patient from the conduit **31**.

The nose blocking device **111** in use rests under the user's nose and blocks the user's nares.

In this third form the headgear and particularly the curved member **34** is substantially the same as that described in relation to the first embodiment.

A fourth embodiment of the patient interface and headgear of the present invention is shown in FIG. **12**. In this embodiment a mouthpiece **120**, **121** is attachable via a tubular extension **122** to the mask base **22**. The mouthpiece is made up of an outer mouthpiece flap **120** and an inner vestibular shield **121**. The shield **121** is substantially the same as that described in reference to the third embodiment. The outer mouthpiece flap **120** rests in use outside the user's mouth and substantially seals about the user's mouth. The outer mouthpiece flap **120** and an inner vestibular shield **121** are described in further detail in U.S. Pat. No. 6,679,257, the entire contents of which is herein incorporated by reference.

In the fourth form of the headgear and particularly the curved member **34** is substantially the same as that described in relation to the first embodiment.

A fifth form of the patient interface and headgear of the present invention is shown in FIGS. **13** and **14**. This embodiment is very similar to the fourth embodiment except the mouthpiece is simply an outer mouthpiece flap **130**. This flap **130** is fittable to the mask base **22** by way of the tubular extension **131**. Again, as above, the headgear and particularly the curved member **34** are substantially the same as that described in relation to the first embodiment.

A sixth form of the patient interface and headgear of the present invention is shown in FIG. **15**. In this embodiment the patient interface is a full face mask **140** that extends over a user's nose and mouth and under the user's chin in use. The mask **140** has a body **142** made from a substantially rigid plastics material and a cushion **144** made from a substantially soft plastics material. The mask and cushion are preferably similar to that described in more detail in U.S. patent application Ser. No. 11/368,004, the entire contents of which is incorporated herein by reference.

A tubular inlet port **143** is formed in the mask body **142**. The tubing **31** is attachable to the port **143** to provide gases to the user wearing the mask.

The headgear is substantially similar to that described in relation to FIG. **2** (the second form); however, the curved member **141** differs. The curved member **141** does not have a mask base similar to that described in the second form in which to attach to. Therefore, the curved member **141** has a central section **145** that curves under the inlet port **143**, effectively anchoring on the inlet port. The curved member **141** is moulded in substantially the same manner as described with reference to the second form.

A seventh form of the patient interface and headgear of the present invention is shown in FIGS. **16** and **17**. Here, the headgear and curved member is similar to that described above in the sixth embodiment, where the curved member **141** has a central section that curves under and anchors onto an inlet port **151** on a patient interface **150**. The patient interface **150** is an integral mouth mask **152** and nasal pillows **153**. The mouth mask **152** preferably extends under the user's **155** chin, as shown in FIG. **17**.

The interface **150** has a substantially rigid body **154** that has substantially soft cushion **156** attached to it. The cushion **156** is preferably of the type disclosed in U.S. Pat. No. 6,951,218 (the entire contents of which is incorporated herein by reference) having an inner **157** and outer **158** cushions.

Integrally formed in the outer cushion **158** are nasal pillows **153**. Preferably two nasal pillows **159**, **160** are formed in the cushion **158**. These are substantially tubular and carry gases in use from the inside of the interface **150** to the user's **155** nares. The outer cushion **158** and nasal pillows **159**, **160** are preferably made from a soft pliable plastics material such as silicone but other appropriate materials such as rubber or KRATON™ may be used.

A similar but slightly different embodiment to that of FIG. **16** is a ninth embodiment of the present invention, as shown in FIG. **23**. Here the interface **400** is substantially the same as the interface **150** of FIGS. **16** and **17**. The interface **400** has a body **401** with integral nasal pillows **402**, **403**. The nasal pillows may be integrally formed with the body or separately formed and simply assembled to the body before use. The nasal pillows **402**, **403**, as above, are substantially tubular and carry gases in use from the inside of the interface **400** to the user's nares. Again, nasal pillows are preferably made from a soft pliable plastics material such as silicone but other appropriate materials such as rubber or KRATON™ may be used.

In this embodiment the body **401** may be made of a more rigid material than the nasal pillows or simply be made from a soft pliable plastics material as are the nasal pillows.

Attached to an inlet **404** of the body **401** is an elongate member **405** similar to that described in any of the embodiments detailed above, but particularly that of FIGS. **20** to **22**. The elongate member **405** has arms **406**, **407** that extend along a user's cheekbones then up towards the user's ears when in use. The arms **406**, **407** are preferably made from a

substantially rigid material, preferably a plastics material. For the users comfort each of the arms **406**, **407** have inner pads (only one pad **408** is shown in FIG. **23**) extending along their inner sides, particularly where the arms are incident on the user's face.

The arms **406**, **407** have recesses **409**, **410** at there ends to which headgear straps **411**, **412** are attached. The arms **406**, **407** may also each have optional side hooks (of which only one side hook **413** is shown), again made out of a substantially rigid material, to which additional side headgear straps **414**, **415** may be attached.

At the centre of the elongate member **405** is formed an integral inlet **416** that matches and attaches to the inlet **404** on the body. This integral inlet **416** receives a conduit or tube **417** that is connected in use to a supply of gases. Preferably the tube **417** has a swivelable elbow **418** (for example, a ball joint socket similar to the one described above). Preferably on the elbow **418** are a number of holes **419** that provide an exhaust vent for gases exhaled by the patient in use.

In this ninth embodiment of the patient interface and headgear the interface is a mouth mask and nasal pillows. In alternative forms the patient interface may be a full face mask that is attached to an elongate member and headgear similar in form to those described above and particularly in relation to FIG. **23**.

The invention claimed is:

1. A patient interface comprising:

a mask assembly having:

a mask body including two nasal pillows extending from it, which in use rest in a substantially sealed manner against the nares of a user, the mask body sized and shaped to leave the mouth of the user uncovered by the mask body when in use;

a ring engaged with the mask body;

a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane;

an elbow rotatably engaged with the ring, the ring forming a socket into which a portion of the elbow fits to facilitate the rotatable engagement between the elbow and the ring, the elbow comprising a plurality of vent holes; and

a tube or conduit extending from the elbow; and

a headgear assembly having:

two side straps that pass down the cheeks of the user to secure the mask body to a face of the user;

a top strap including a buckle configured to facilitate length adjustment of the top strap; and

a back strap adjustably connected to at least one of the top strap and the two side straps;

wherein the two side straps are configured to connect and disconnect with the mask assembly while the elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body wherein the mask assembly is configured to connect to only the two side straps; and

wherein the top strap connects only with one or more of the side straps and the back strap.

2. A patient interface as claimed in claim **1**, wherein the mask body includes a lip and the ring includes a channel receiving the lip of the mask body.

3. A patient interface as claimed in claim **2**, wherein the mask body comprises a molded elastomeric material.

4. A patient interface as claimed in claim **1**, wherein the elbow is able to swivel in the ring such that the tubing is available to be adjacent to either side strap.

5. A patient interface as claimed in claim **1**, wherein the ring comprises a hard plastic material.

6. A patient interface as claimed in claim **1** further comprising molded side arms extending away from the ring to connect with the side strap, the molded side arms connecting to the side straps that pass down the cheeks of the user.

7. A patient interface as claimed in claim **1**, wherein, in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows.

8. A patient interface comprising:

a mask assembly having a mask body, the mask body comprising a substantially flexible elastomeric material, the mask body comprising a first nasal pillow and a second nasal pillow, the first nasal pillow and the second nasal pillow being angled toward one another, the first nasal pillow comprising a first generally conical portion and a first generally cylindrical portion, the second nasal pillow comprising a second generally conical portion and a second generally cylindrical portion, the first nasal pillow comprising a first outlet opening and the second nasal pillow comprising a second outlet opening, the mask body also comprising a mask body inlet opening, the mask body inlet opening being spaced apart from the first outlet opening and the second outlet opening, the mask body sized and shaped to leave the mouth of a user uncovered by the mask body when in use, the mask body inlet opening comprising a generally circular opening into the mask body the mask assembly having a ring-like connector releasably connected to the mask body inlet, wherein a plane bisects the ring-like connector and the first nasal pillow is located on a side of the plane opposite the second nasal pillow;

a tube assembly configured to deliver airflow to the mask body, the tube assembly comprising a flexible conduit, the flexible conduit comprising a first end and a second end, the first end of the flexible conduit comprising a connector, the second end of the flexible conduit comprising an elbow, the elbow comprising a wall, the wall comprising a vent, the vent comprising a plurality of holes extending through the wall of the elbow, the ring-like connector end being secured around an outer portion of the elbow, the elbow and the mask body being connected at least in part by the ring-like connector end such that airflow from the tube assembly can be directed from the elbow through the generally circular opening of the mask body and into the mask body, the elbow and the mask body being capable of rotating relative to each other; and

a headgear assembly configured to secure the mask body to a face of the user, the headgear assembly comprising a first side strap and a second side strap, a top strap being connected to the first side strap and the second side strap, the top strap including buckle configured to adjust a length of the top strap, and a back strap adjustably connected to at least one of the top strap, the first side strap, and the second side strap;

wherein the first side strap and the second side strap are configured to connect and disconnect with the mask assembly while the elbow is connected with the mask body, wherein the mask assembly is configured to connect to only two side straps, and wherein top strap connects only with one or more of the first side strap, the second side strap, and the back strap.

9. A patient interface comprising:

a mask assembly having:

a mask body comprising a molded elastomeric material, the mask body comprising two nasal pillows and a lip, the two nasal pillows, in use, resting in a substantially sealed manner against corresponding nares of a user, the mask body sized and shaped to leave the mouth of a user uncovered by the mask body when in use;

a ring of a hard plastic material engaged with the lip of the mask body;

a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane;

an elbow rotatably engaged with the ring such that a portion of the elbow is received within the ring, the elbow comprising a wall, a vent comprising a plurality of holes in the wall of the elbow; and

a tube or conduit extending from the elbow; and

a headgear assembly having:

a top strap removably connected to side straps, the side straps adapted to pass down the cheeks of the user, the elbow being able to swivel in the ring such that the tube or conduit can be positioned adjacent to either side strap or can fall freely; and

a back strap adjustably connected with one or more of the top strap and the side straps;

wherein the side straps are configured to connect and disconnect with the mask body while elbow is rotatably engaged with the ring and the ring is engaged with the mask body wherein the mask assembly is configured to connect to only two side straps, and wherein the top strap connects only with one or more of the side straps and the back strap.

10. A patient interface as claimed in claim **9**, wherein the ring comprises a channel receiving the lip of the mask body.

11. A patient interface as claimed in claim **9**, wherein the two nasal pillows are angled toward one another.

12. A patient interface as claimed in claim **9** further comprising two molded side arms that extend away from the mask body to connect with the two side straps.

13. A patient interface as claimed in claim **9**, wherein the two side arms overlap a portion of the two side straps.

14. A patient interface as claimed in claim **9**, wherein, in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows.

15. A patient interface as claimed in claim **9**, wherein each of the two nasal pillows comprises an inner profile and an outer profile, the inner profile defining an outlet of the nasal pillow, and the inner profile being offset inward relative to the outer profile.

16. A patient interface as claimed in claim **9**, wherein each of the two nasal pillows comprises an inner profile and an outer profile, the inner profile defining an outlet of the nasal pillow, and the inner profile being offset downward relative to the outer profile such that, in use, the inner profile is offset toward the user's lip relative to the outer profile.

17. A patient interface as claimed in claim **1**, wherein the ring comprises a first wall and a second wall defining a space therebetween, and wherein a portion of the mask body is configured to removably attach to the ring via friction within the space and with the first wall and the second wall.

18. A patient interface as claimed in claim **1**, wherein the top strap is integrally formed with one or more of the side straps and the back strap.

19. A patient interface as claimed in claim **18**, wherein the top strap is integrally formed with one or more of the side straps.

20. A patient interface as claimed in claim **8**, wherein the top strap is integrally formed with one or more of the side straps and the back strap.

21. A patient interface as claimed in claim **20**, wherein the top strap is integrally formed with one or more of the side straps.

22. A patient interface as claimed in claim **9**, wherein the top strap is integrally formed with one or more of the side straps and the back strap.

23. A patient interface as claimed in claim **22**, wherein the top strap is integrally formed with one or more of the side straps.

24. A patient interface as claimed in claim **1**, wherein the top strap is releasably connected to one or more of the side straps and the back strap.

25. A patient interface as claimed in claim **24**, wherein the top strap is releasably connected to the back strap.

26. A patient interface as claimed in claim **8**, wherein the top strap is releasably connected to one or more of the side straps and the back strap.

27. A patient interface as claimed in claim **26**, wherein the top strap is releasably connected to the back strap.

28. A patient interface as claimed in claim **9**, wherein the top strap is releasably connected to one or more of the side straps and the back strap.

29. A patient interface as claimed in claim **28**, wherein the top strap is releasably connected to the back strap.

* * * * *

EXHIBIT 2

US008479741B2

(12) **United States Patent**
McAuley et al.

(10) **Patent No.: US 8,479,741 B2**
(45) **Date of Patent: Jul. 9, 2013**

(54) **BREATHING ASSISTANCE APPARATUS**

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(73) Assignee: **Fisher & Paykel Healthcare Limited**, Auckland (NZ)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1157 days.

(21) Appl. No.: **12/353,640**

(22) Filed: **Jan. 14, 2009**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 12/307,993, filed as application No. PCT/NZ2007/000185 on Jul. 13, 2007.

(30) **Foreign Application Priority Data**

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Nov. 6, 2006 (NZ) 551103

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A61M 11/00 (2006.01)

(52) **U.S. Cl.**
USPC **128/207.18**; 128/206.24; 128/207.11; 128/207.13

(58) **Field of Classification Search**
USPC 128/207.18, 206.21, 206.24, 206.27, 128/207.11, 207.13
See application file for complete search history.

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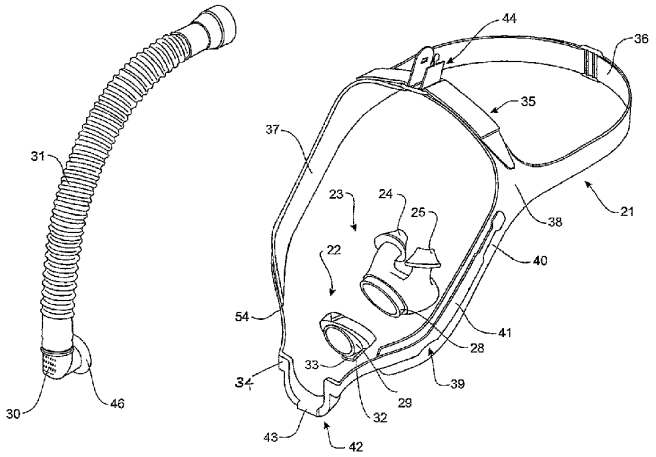
Primary Examiner — Steven Douglas
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear LLP

(57) **ABSTRACT**

Headgear for use with a respiratory mask is described. The headgear includes a continuous and substantially curved elongate member extending in use below a user's nose and at least two headgear straps capable of attachment to the ends of the elongate member. A mask attachment on the elongate member is disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask. The attachment is capable of receiving the mask.

36 Claims, 21 Drawing Sheets



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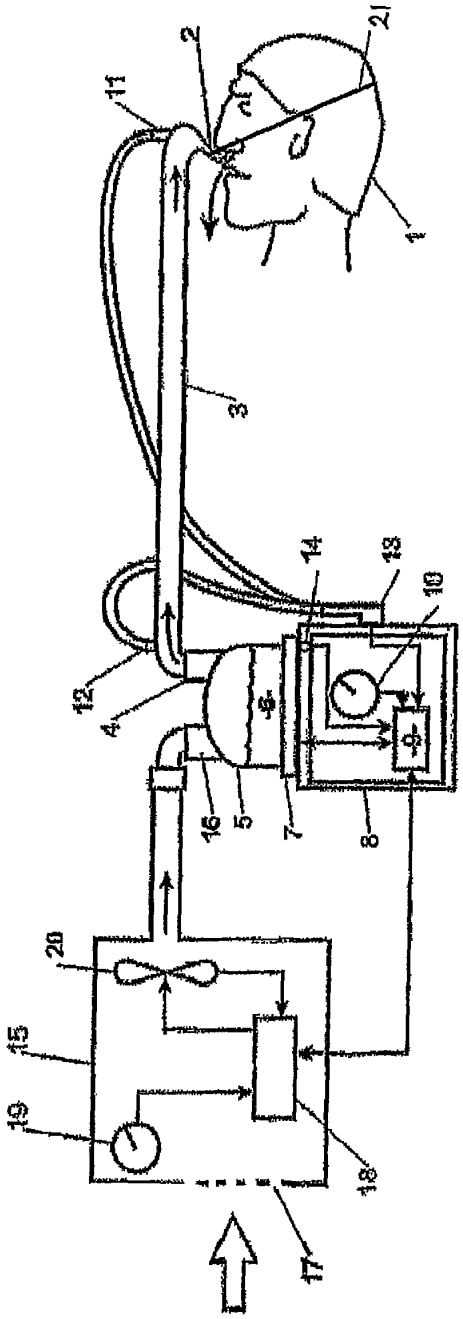

FIGURE 1

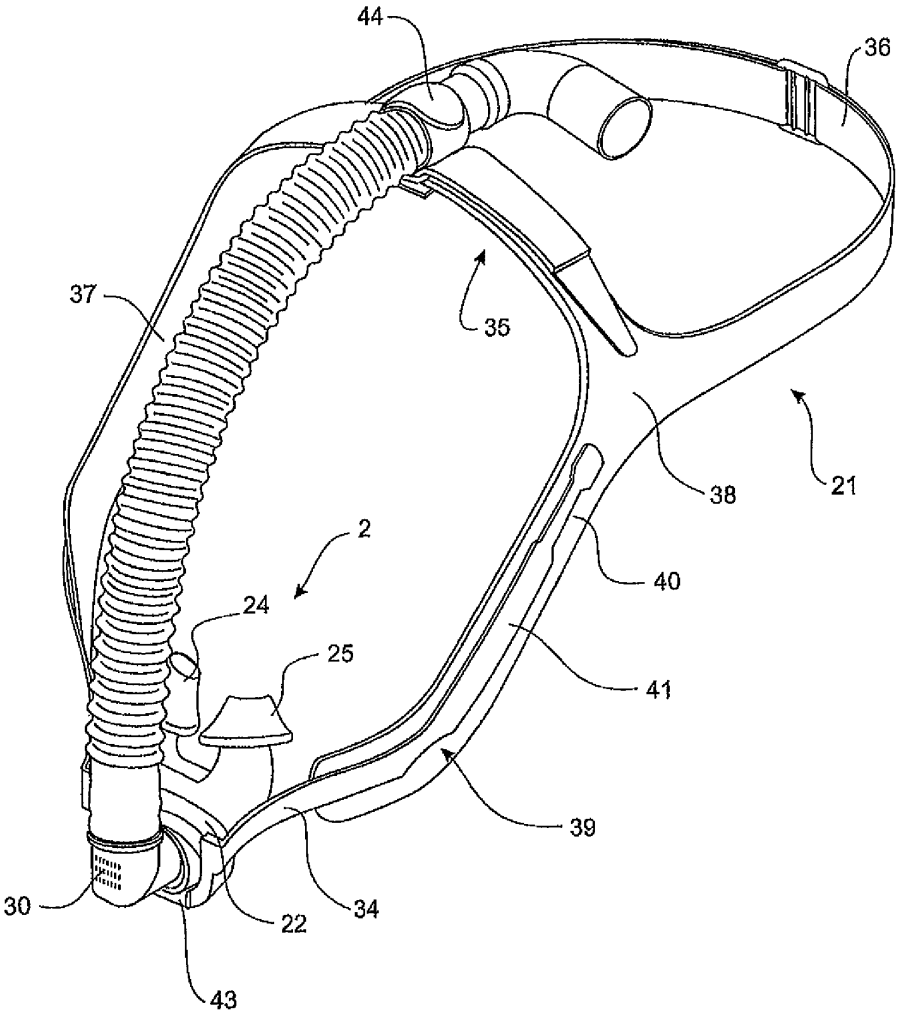

FIGURE 2

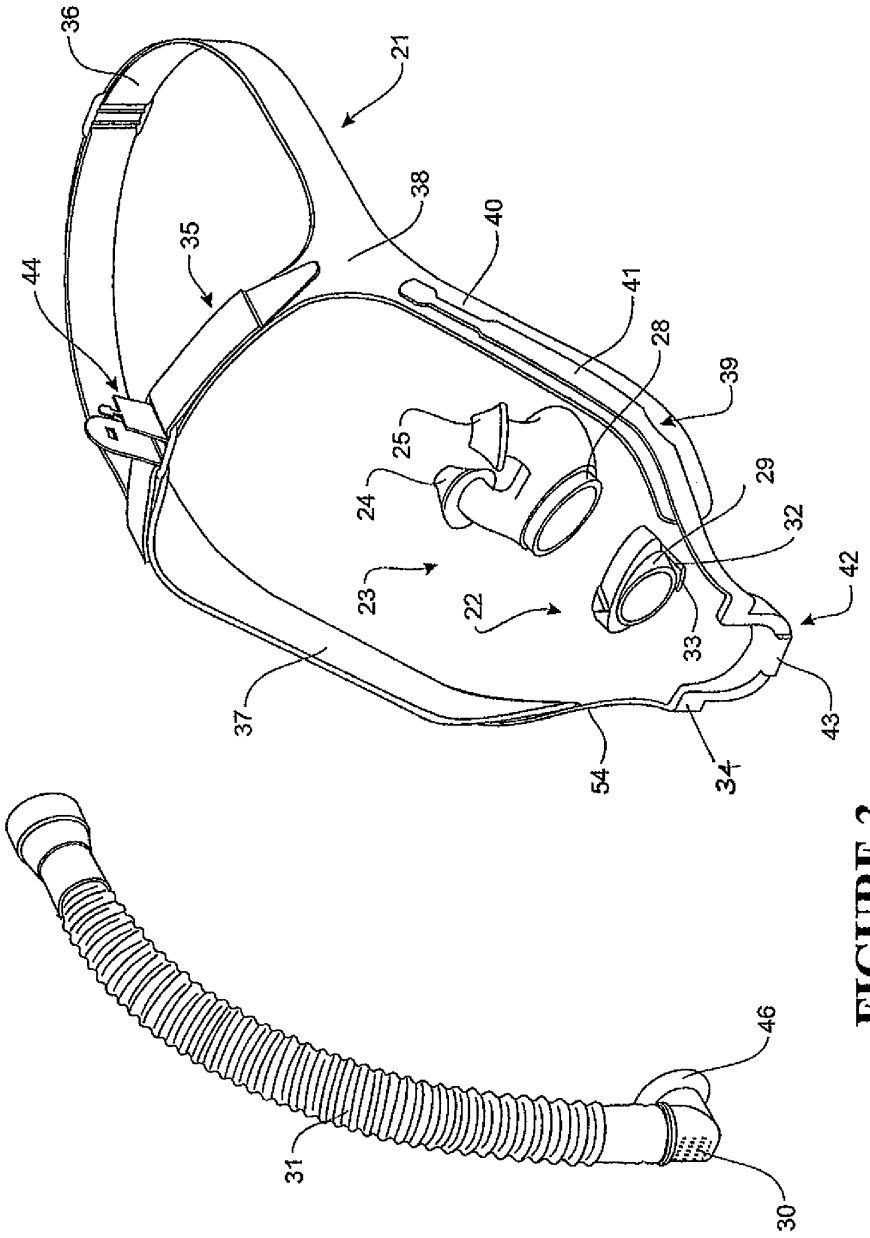

FIGURE 3

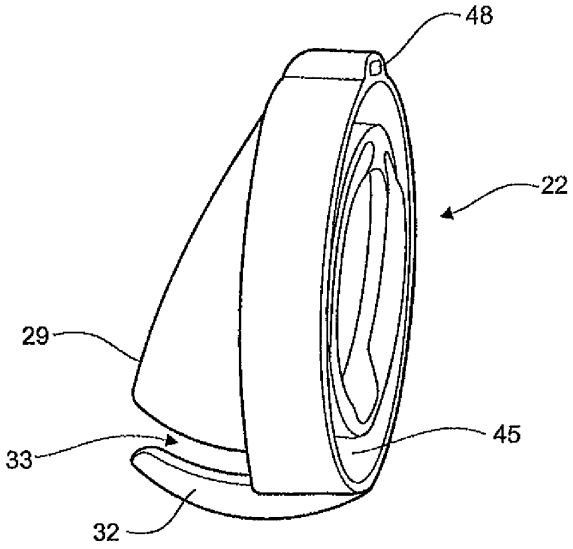

FIGURE 4

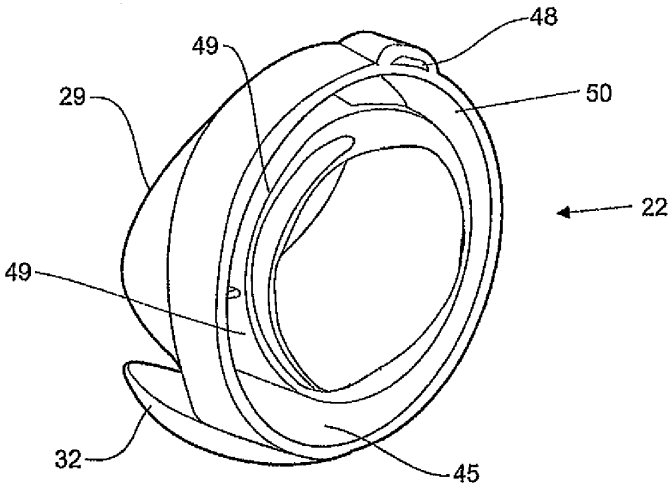

FIGURE 5

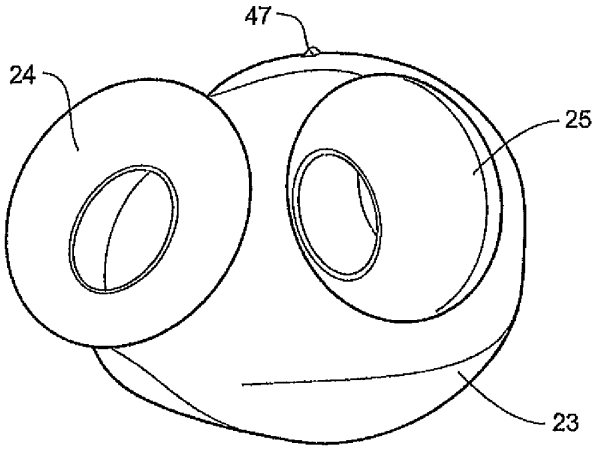

FIGURE 6

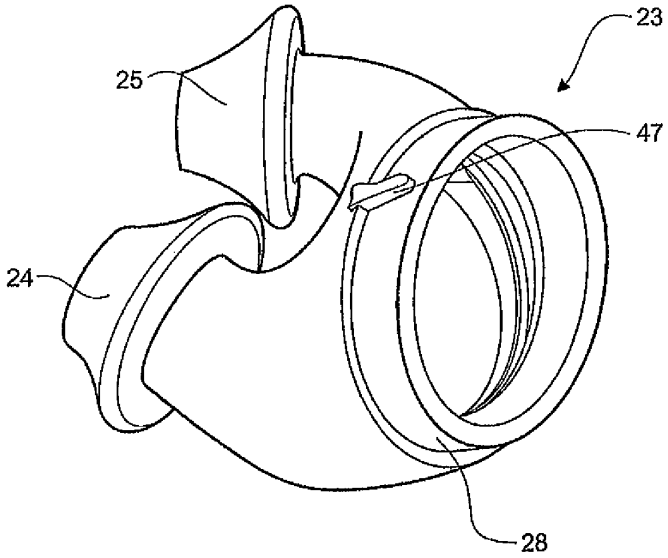

FIGURE 7

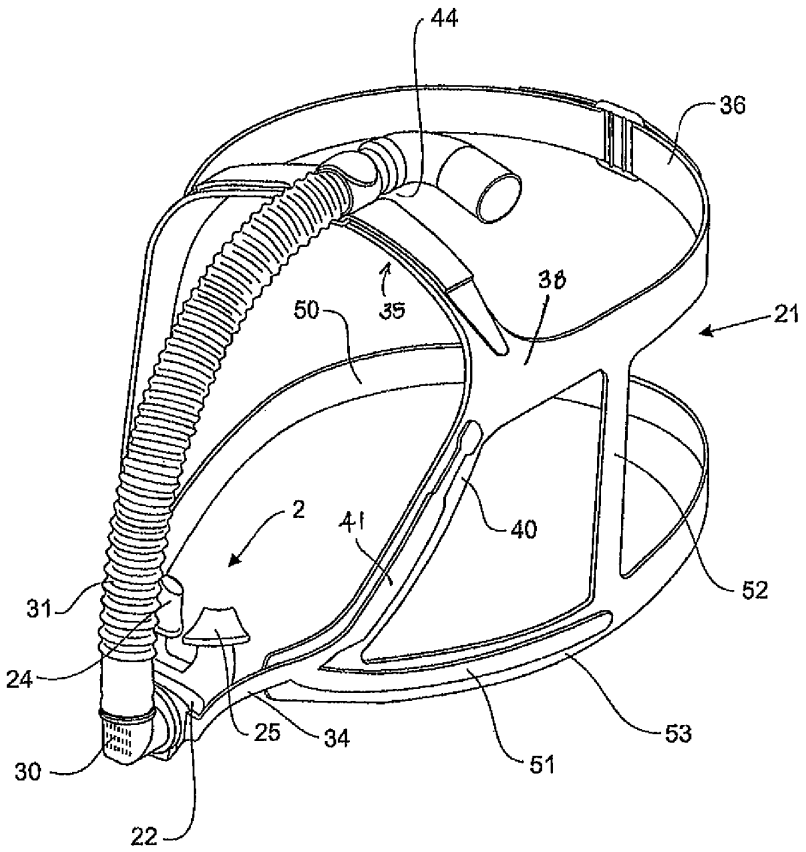

FIGURE 8

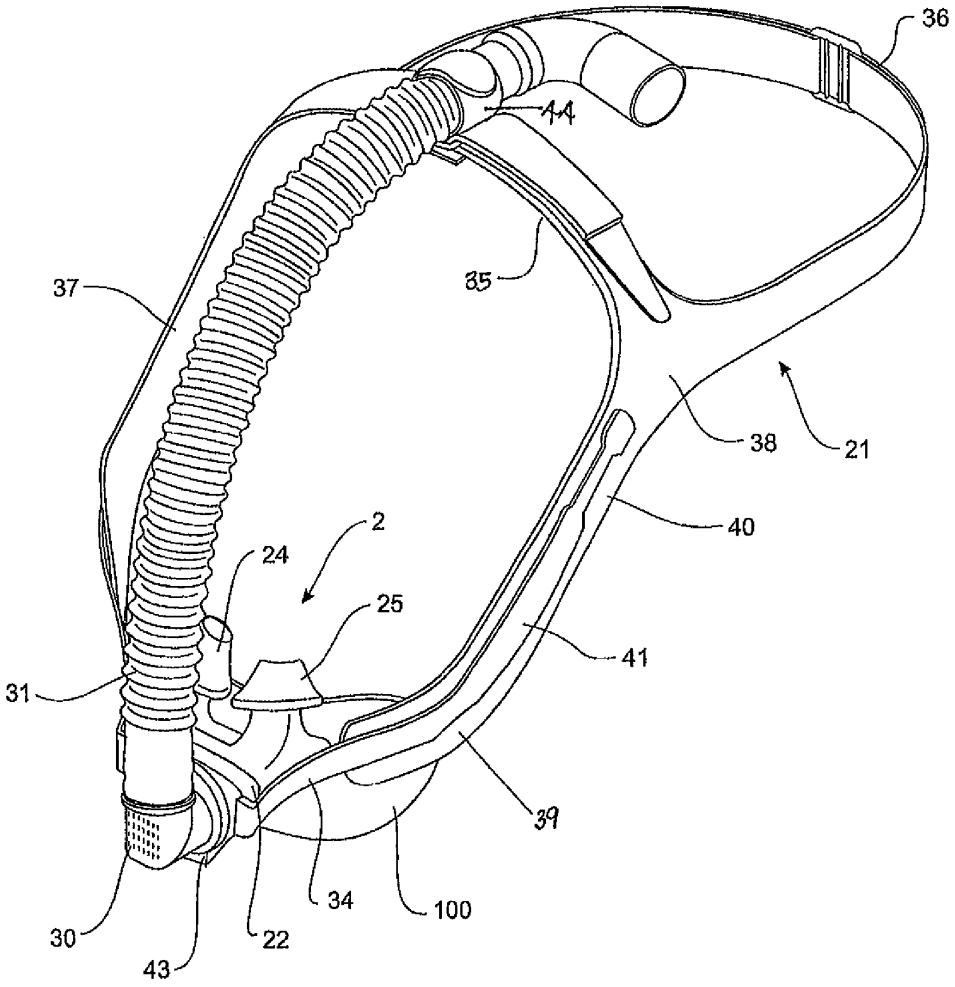

FIGURE 9

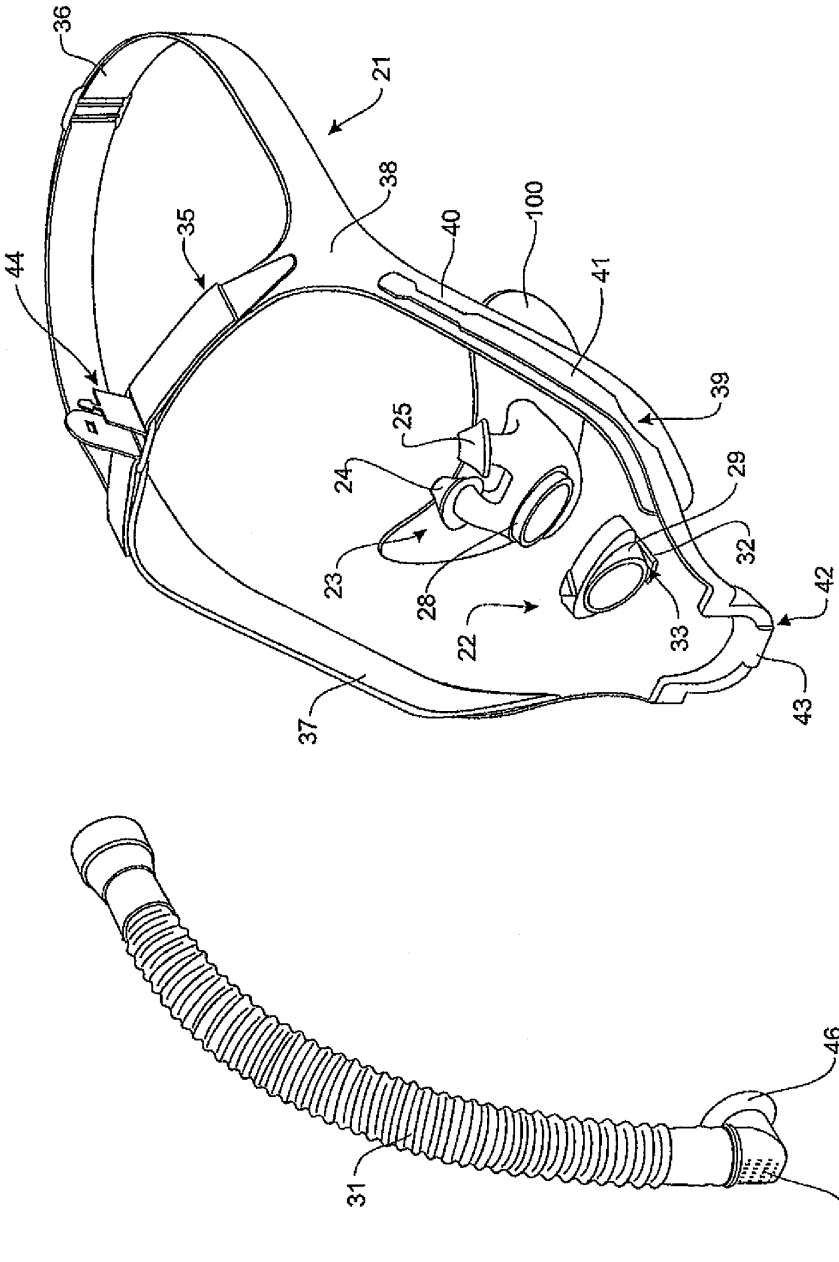

FIGURE 10

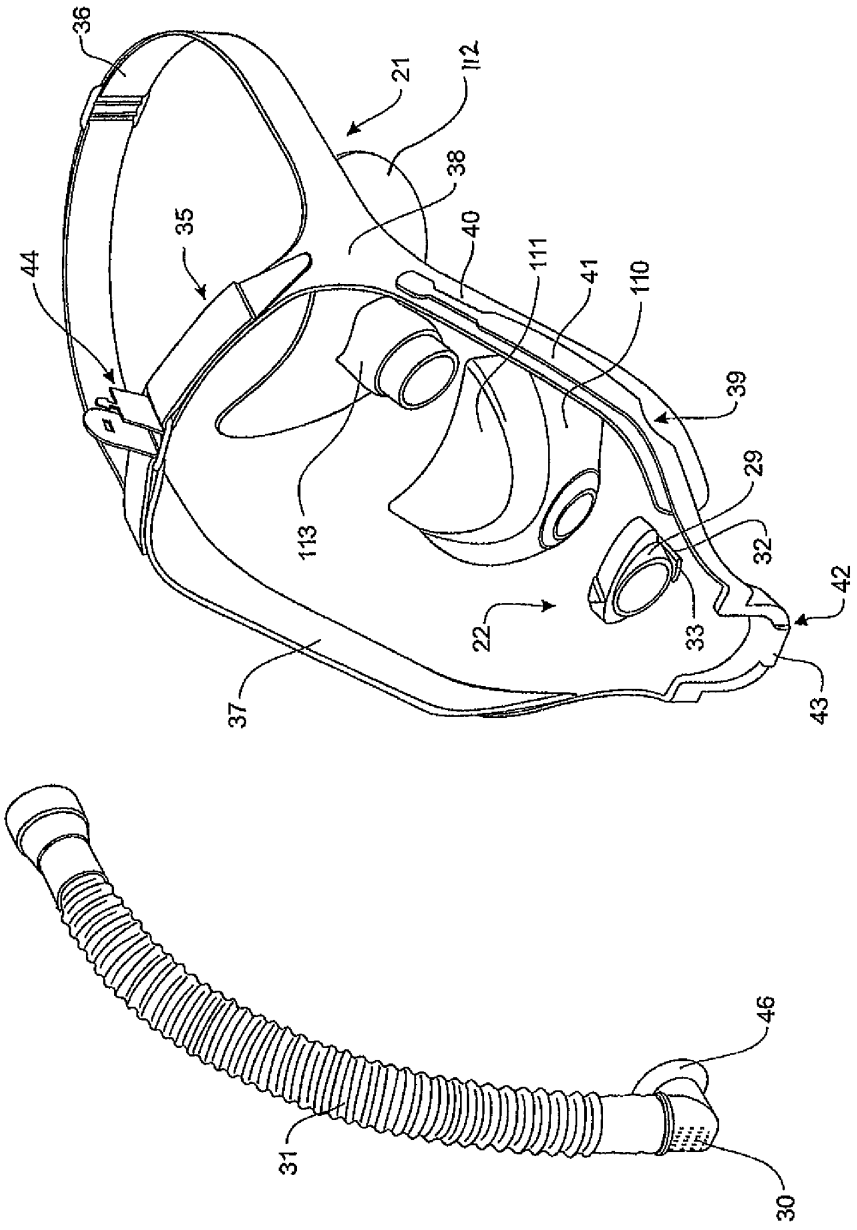

FIGURE 11

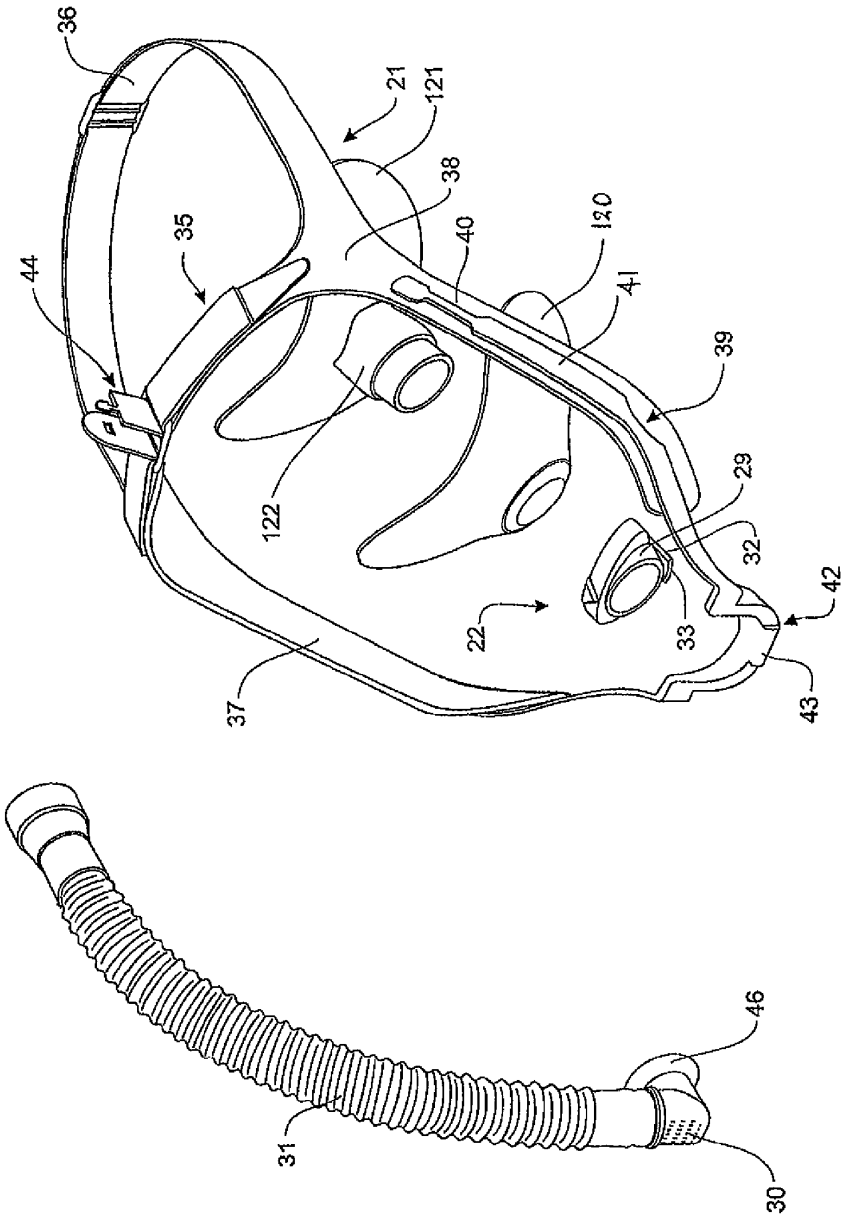

FIGURE 12

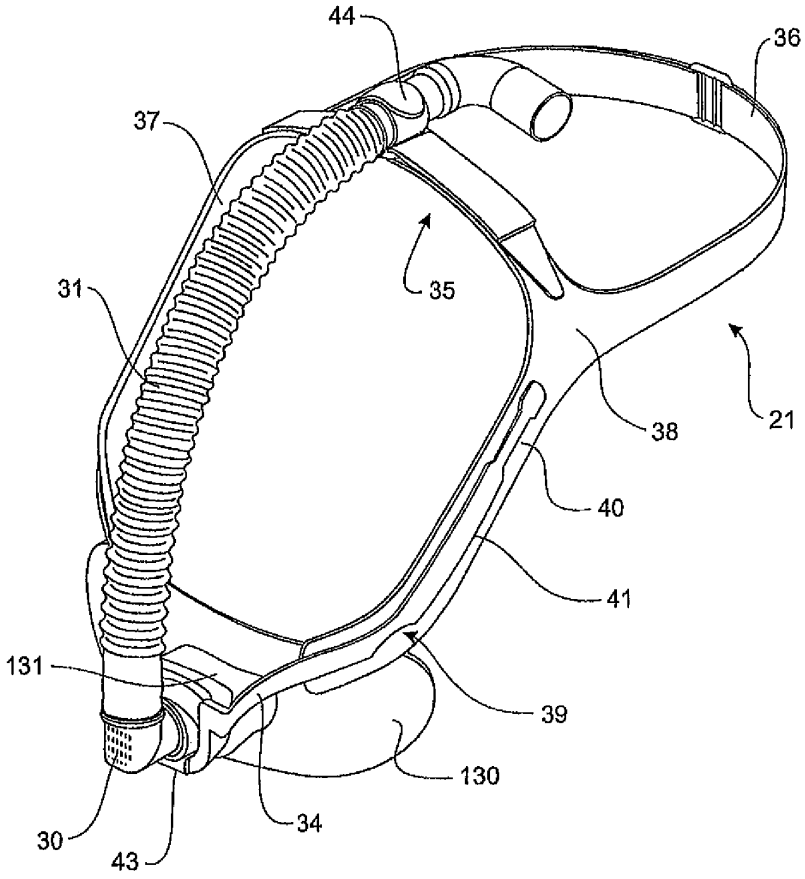

FIGURE 13

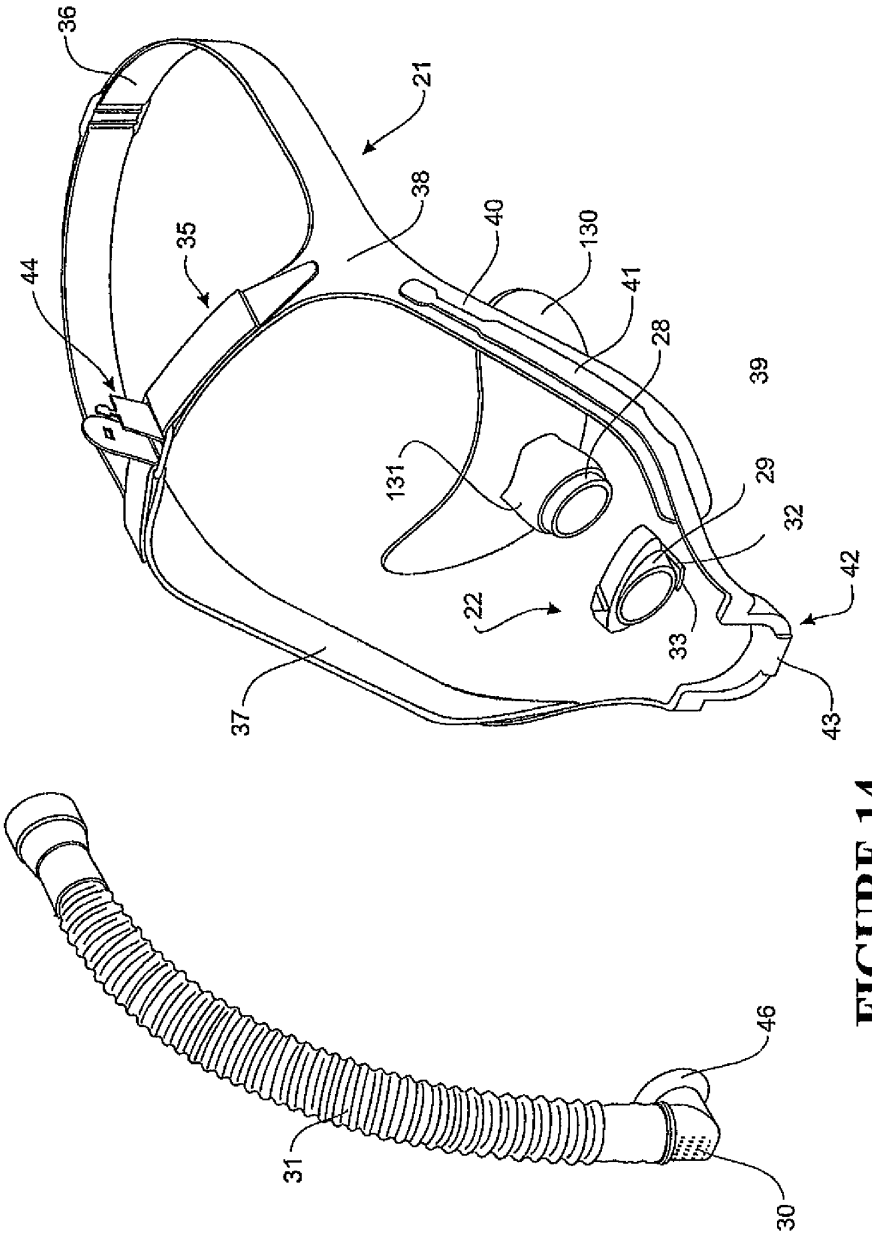

FIGURE 14

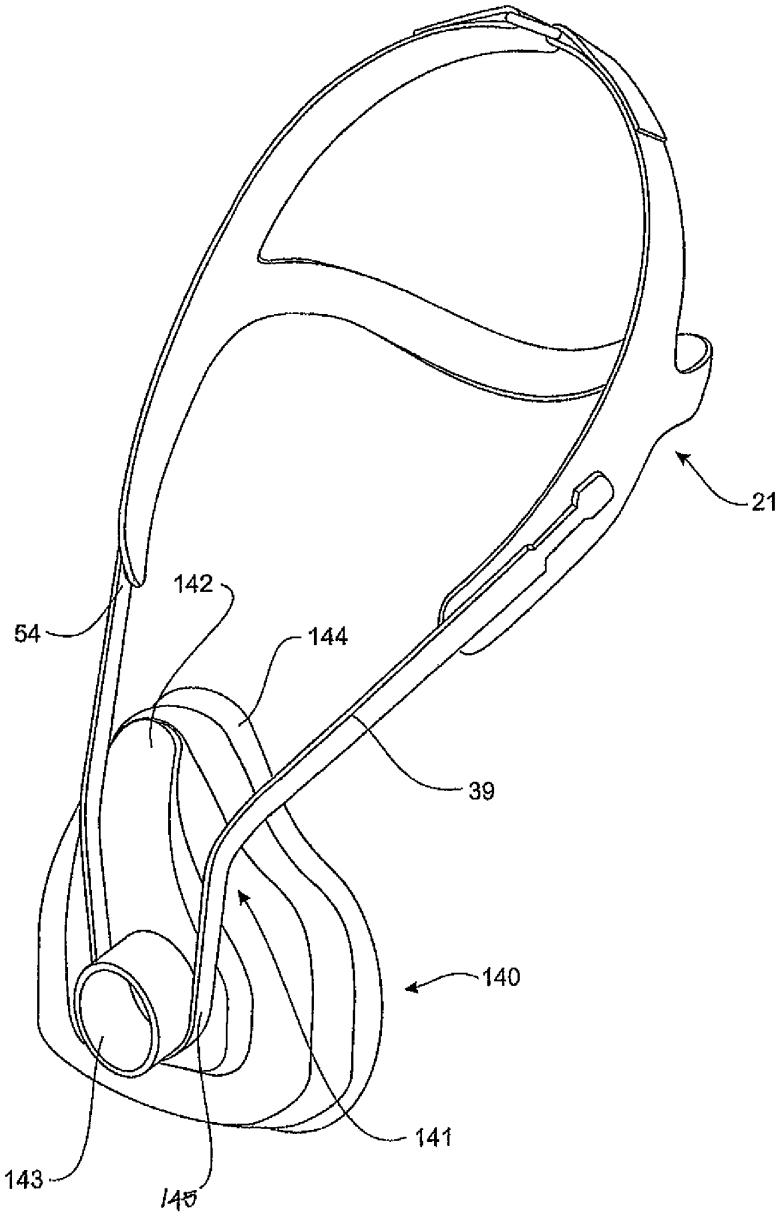

FIGURE 15

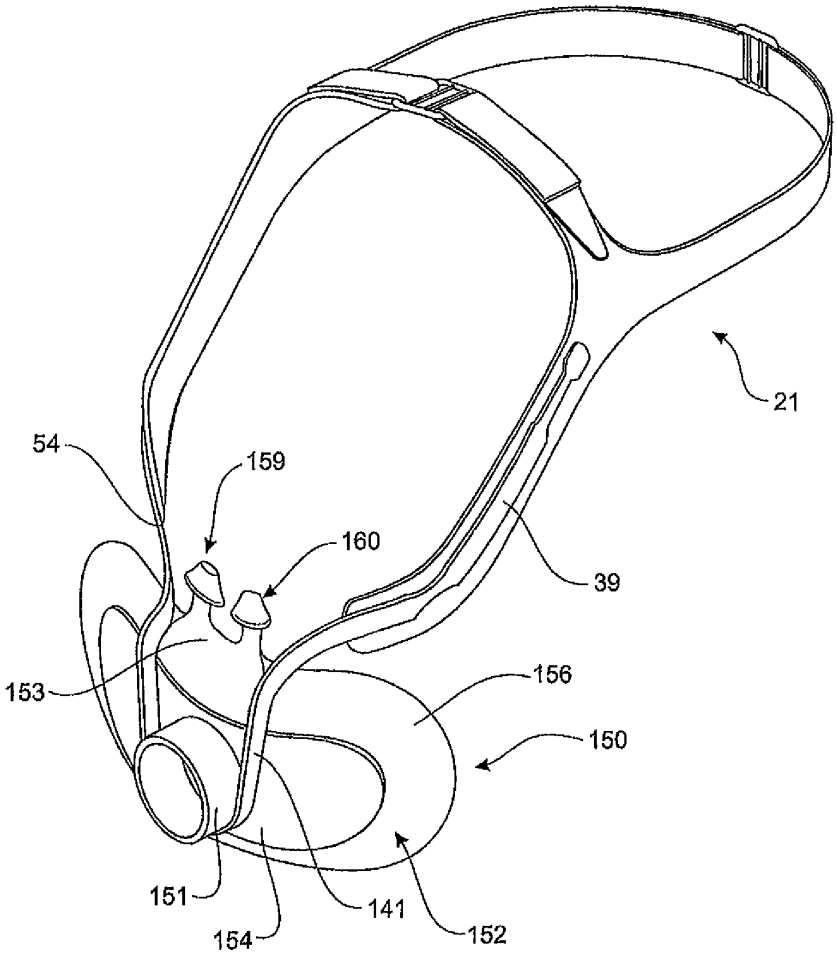

FIGURE 16

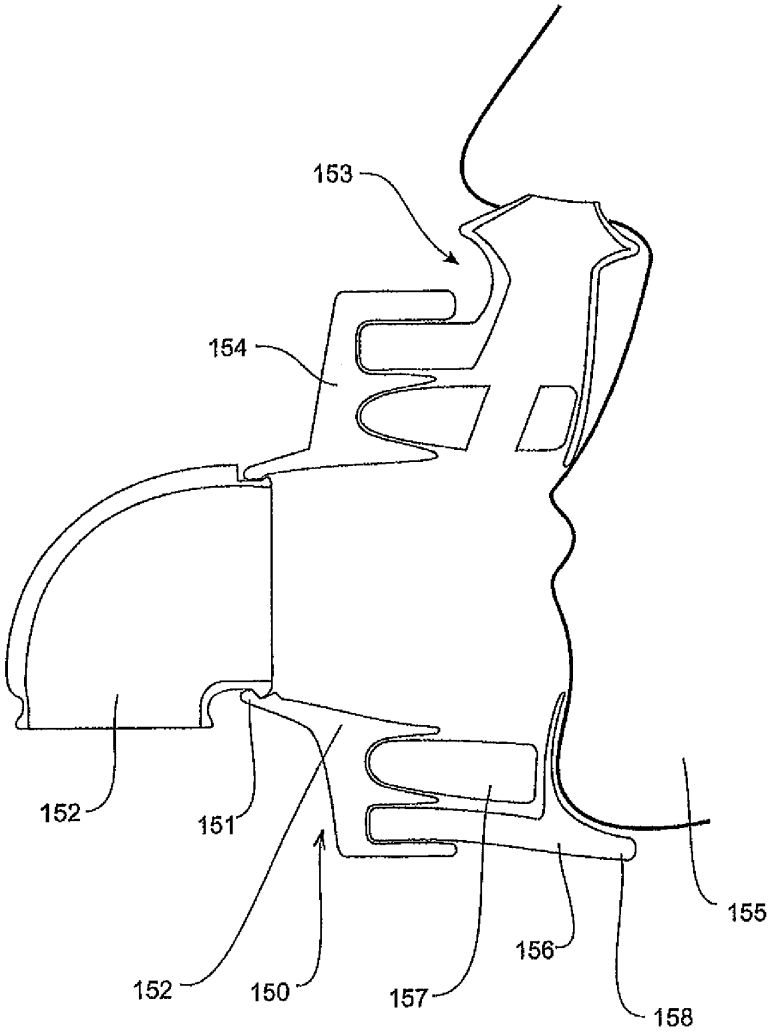

FIGURE 17

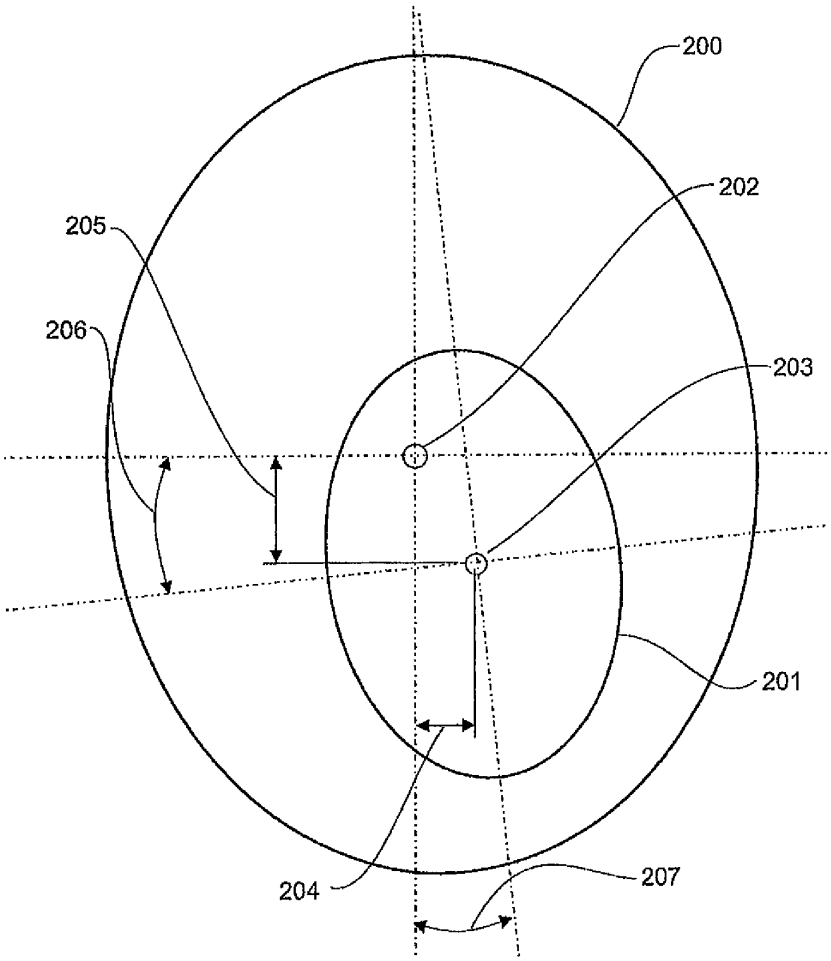

FIGURE 18

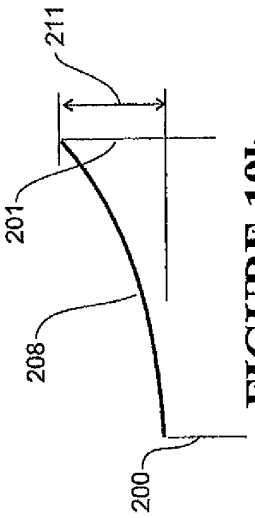

FIGURE 19b

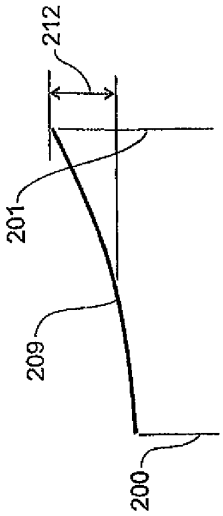

FIGURE 19c

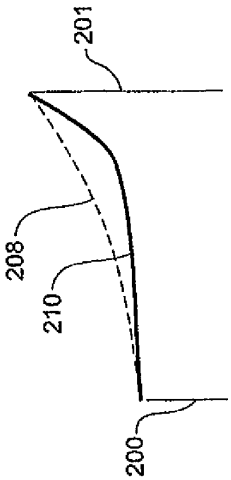

FIGURE 19d

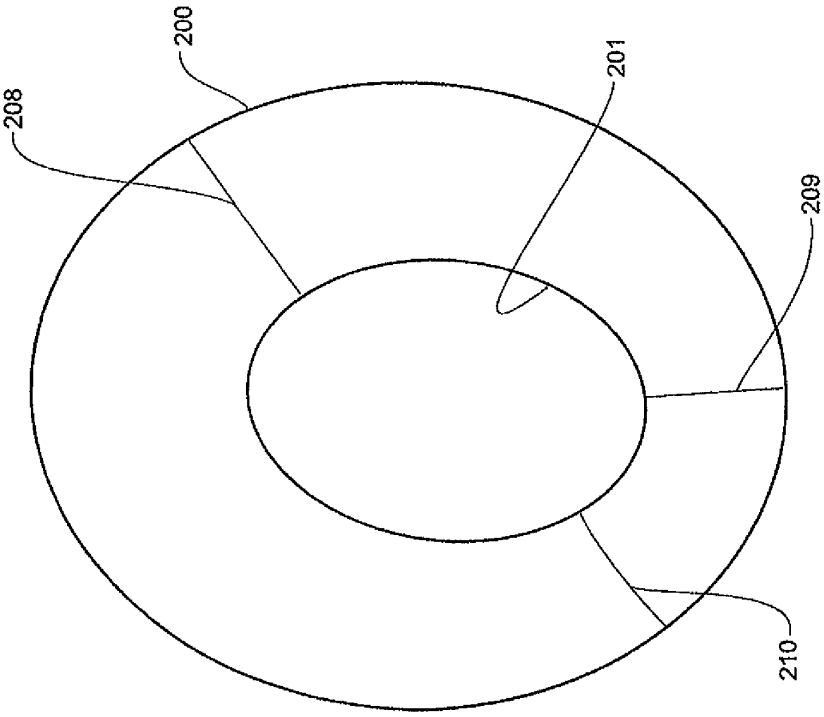

FIGURE 19a

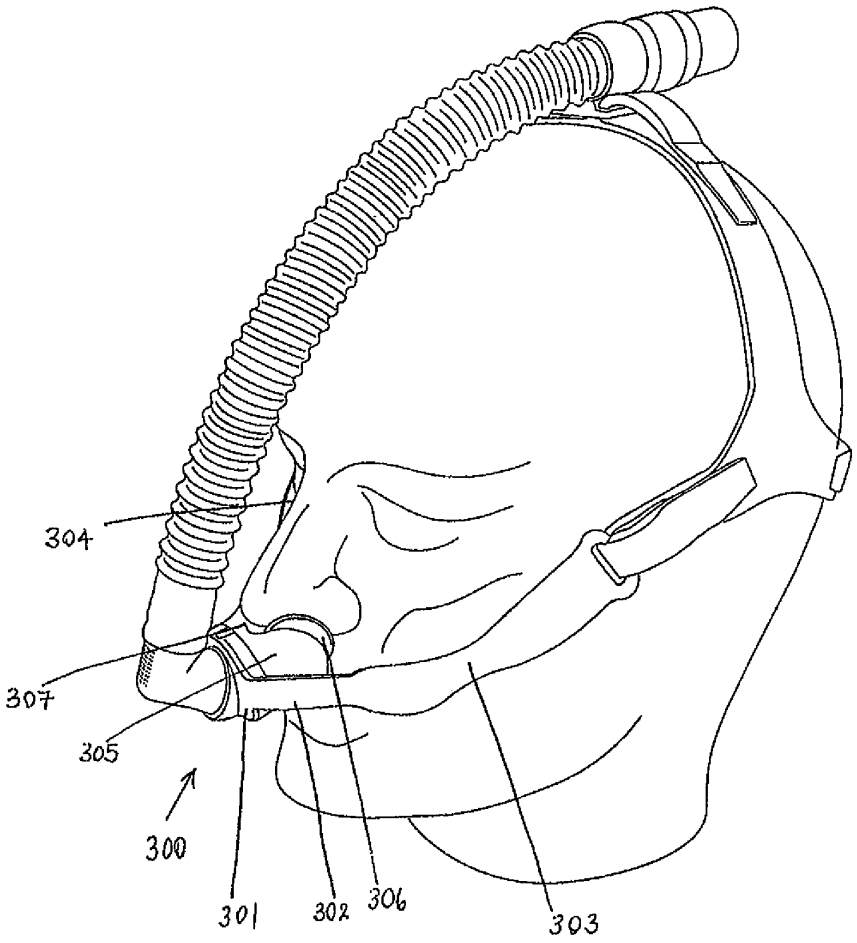

FIGURE 20

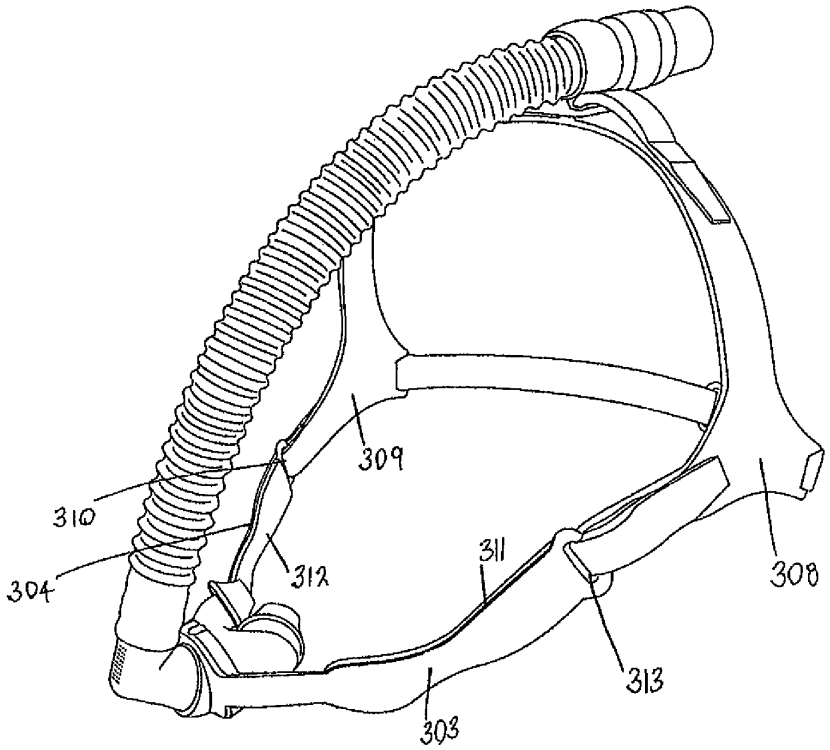

FIGURE 21

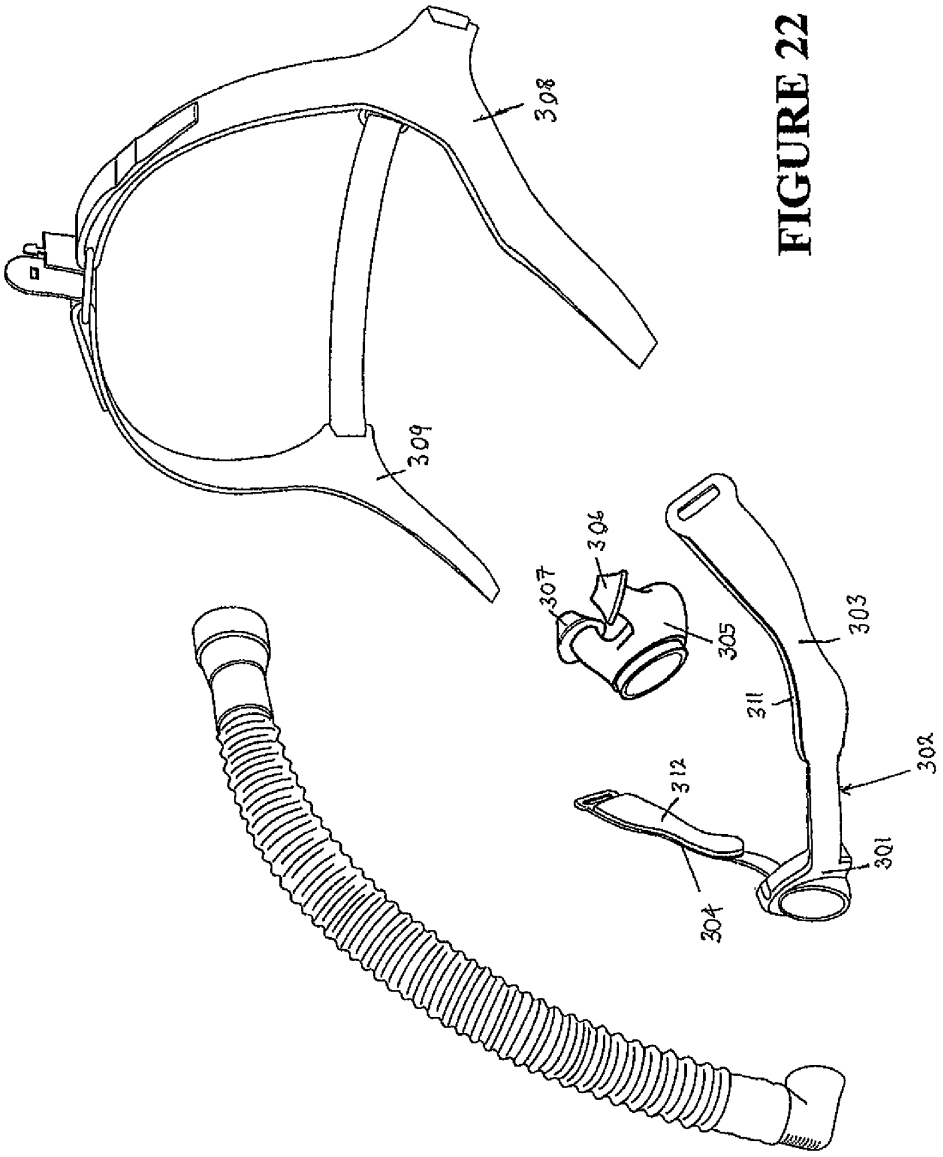

FIGURE 22

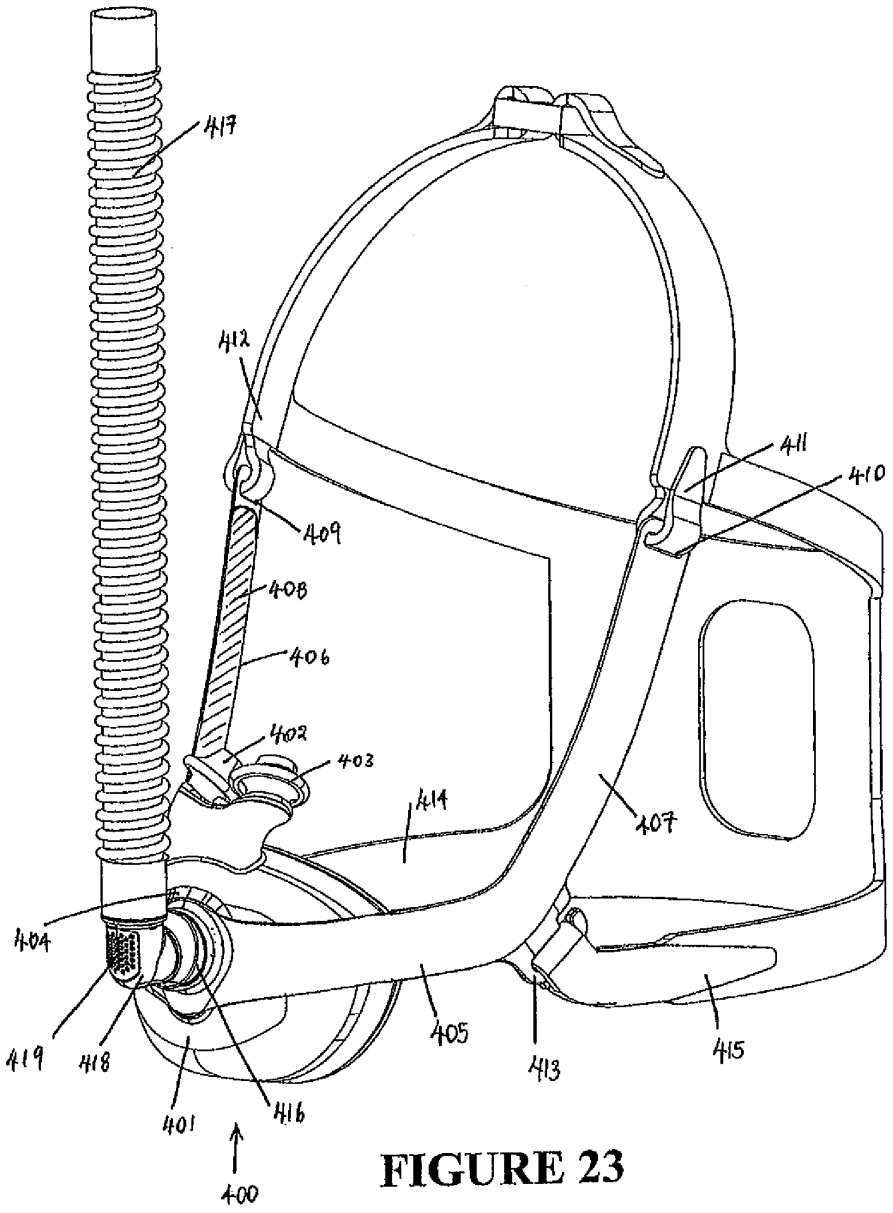
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FIGURE 23

BREATHING ASSISTANCE APPARATUS

This application is a continuation of U.S. patent application Ser. No. 12/307,993, entitled "Breathing Assistance Apparatus" which has a filing date of Jan. 8, 2009, which is a National Phase application of PCT/NZ2007/000185 having an international filing date of Jul. 13, 2007, and which claims priority of New Zealand Patent Nos. 548575, filed on Jul. 14, 2006 and 551103, filed on Nov. 6, 2006, all of which are hereby incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

1. Technical Field

The present invention relates to apparatus for treating sleep apnoea. More specifically, the present invention provides a nasal interface for the supply of respiratory gases, but most particularly positive pressure gases.

2. Summary of the Prior Art

In the art of respiration devices, a variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face are well known. Masks that provide gas at positive pressure within the mask for consumption by the user are also well known. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

Obstructive Sleep Apnoea (OSA) is a sleep disorder that affects up to at least 5% of the population in which muscles that normally hold the airway open relax and ultimately collapse, sealing the airway. The sleep pattern of an OSA sufferer is characterised by repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep. Often the sufferer is unaware of this pattern occurring. Sufferers of OSA usually experience daytime drowsiness and irritability due to a lack of good continuous sleep.

In an effort to treat OSA sufferers, a technique known as Continuous Positive Airway Pressure (CPAP) was devised. A CPAP device consists of a gases supply (or blower) with a conduit connected to supply pressurised gases to a patient, usually through a nasal mask. The pressurised air supplied to the patient effectively assists the muscles to keep the patient's airway open, eliminating the typical OSA sleep pattern.

The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4 to 20 cm H2O. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery hose to a nose, full face, nose and mouth, or oral mask that is sealingly engaged to a patient's face, preferably by means of a harness or other headgear. An exhaust port is usually also provided in the delivery tube proximate to the mask or on the mask itself. More sophisticated forms of positive airway pressure devices, such as bi-level devices and auto-titrating devices, are described in U.S. Pat. No. 5,148,802 of Respironics, Inc. and U.S. Pat. No. 5,245,995 of Rescare Limited, respectively.

One requisite of respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. A common complaint of a user of CPAP therapy is pressure sores caused by the mask about the nose and face and

in particular in the nasal bridge region of the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days, hi such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

U.S. Pat. No. 5,477,852 of Airways Ltd, Inc. discloses a nasal positive airway pressure device that has a pair of nasal members each having a cannula tip to be inserted into the nares of the patient. Each cannula is tapered from a substantially circular cross section outside the patients nostril to a substantially oval cross section at the tip inserted into the nostril. An inflatable cuff surrounds each cannula with the interior space of the cuff communicating with the lumen of the cannula through at least one aperture in the sidewall of the cannula. The nasal members are connected to one or more flexible hoses that, in turn, are connected to a source of positive air pressure. In use, positive air pressure is supplied to each cannula tip through the air hoses and nasal members. The positive air pressure inflates the cuffs to hold the nasal members in place and to effect treatment. The nasal device of U.S. Pat. No. 5,477,852 is attached to headgear that is located about a patients head. This headgear could be considered by many patients as cumbersome and uncomfortable.

Conventional nasal masks used for administrating CPAP treatment are also considered uncomfortable and cumbersome, and prior art nasal masks can be noisy due to air leaks. These disadvantages in many cases are a formidable obstacle to patient acceptance of such treatment. Therefore, a substantial number of patients either cannot tolerate treatment or choose to forego treatment. It is believed a number of such patients might benefit from a nasal positive airway pressure apparatus that is more convenient to use and comfortable to wear, thereby resulting in increased treatment compliance.

Innomed Technologies, Inc. manufactures a nasal cannula device called the NASALAIRE™.

In this device air or oxygen travels down a wide bore conduit to nasal cannula. The NASALAIRE™ creates a physical seal between the nares and itself, and relies on the absence of leaks around the cannula and the nares to deliver pressure supplied by a continuous positive airway pressure (CPAP) blower to the airway of the wearer.

U.S. Pat. No. 6,119,694 of Respironics Georgia, Inc discloses a nasal mask having a nare seal and lateral support members to support the mask.

WO2004/073778 of ResMed Limited discloses a nasal mask including a frame where headgear is provided with rigid sections that extend to the nasal mask.

WO04/041341 of ResMed Limited discloses headgear for a patient mask that includes a sewn on rigid section to the back area of headgear straps to provide rigidity to the straps. U.S. Pat. No. 6,907,882 of ResMed Limited discloses a nasal mask and headgear that is attachable to the frame of the nasal mask. The headgear straps have rigid sections integral with the releasable connectors that attach the headgear to the mask.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface that goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

In a first aspect the present invention consists in headgear for use with a respiratory mask comprising:

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask, said attachment capable of receiving said mask.

In a second aspect the present invention consists in a breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask having a base and body, said body having two flexible nasal pillows that in use rest in a substantially sealed manner against said user's nares,

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed below said user's nose, said attachment capable of receiving said mask.

In a third aspect the present invention consists in a breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask comprising a body and a cushion, said cushion substantially forming a seal with said patient's airways,

headgear comprising substantially flexible, soft straps and a substantially continuous curved elongate member to which said mask is attached, said elongate member extending over said user's checks, and

wherein said mask has an inlet extension tube and said curved elongate member is attached or rests beneath said inlet extension tube, anchoring said mask to said user's face in use.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE FIGURES

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

FIG. **1** is a block diagram of a humidified continuous positive airway pressure system as might be used in conjunction with the nasal mask of the present invention.

FIG. **2** is a perspective view of a first form of a patient interface that is nasal mask and headgear of the present invention.

FIG. **3** is an exploded view of the nasal mask and headgear of FIG. **2**.

FIG. **4** is a side view of a mask base of the nasal mask and headgear of FIG. **2**.

FIG. **5** is a perspective end view of the mask base of FIG. **4**.

FIG. **6** is an end view of a body of the nasal mask and headgear of FIG. **2**, particularly showing two nasal pillows.

FIG. **7** is a perspective view of the body of FIG. **6**.

FIG. **8** is a perspective view of a nasal mask of the first form of the present invention but having alternative headgear that includes additional rigid extensions.

FIG. **9** is perspective view of a second form of a patient interface and headgear of the present invention.

FIG. **10** is an exploded view of the patient interface and headgear of FIG. **9**.

FIG. **11** is an exploded view of a third form of a patient interface and headgear of the present invention.

FIG. **12** is an exploded view of a fourth form of a patient interface and headgear of the present invention.

FIG. **13** is a perspective view of a fifth form of a patient interface and headgear of the present invention.

FIG. **14** is an exploded view of the patient interface and headgear of FIG. **13**.

FIG. **15** is a perspective view of a sixth form of a patient interface and headgear of the present invention.

FIG. **16** is a perspective view of a seventh form of a patient interface and headgear of the present invention.

FIG. **17** is a cross-sectional view of the patient interface of FIG. **16**.

FIG. **18** is a front view of a nasal pillow of FIG. **6**.

FIG. **19***a* is a front view of the nasal pillows of FIG. **6**.

FIGS. **19***b* to **19***d* are graphs of the gradients of various nasal pillow connecting surfaces.

FIG. **20** is a perspective view of an eighth form of a patient interface and headgear of the present invention.

FIG. **21** is a perspective view of the interface and headgear of FIG. **20** showing inner pads on the arms of the headgear.

FIG. **22** is an exploded view of the interface and headgear of FIG. **20**.

FIG. **23** is a perspective view of a ninth form of a patient interface and headgear the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

The breathing assistance apparatus of the present invention including masks and headgear as described in the preferred embodiments of this invention can be used in respiratory care generally or with a ventilator. It is described below with reference to use in a humidified CPAP system.

A humidified Continuous Positive Airway Pressure (CPAP) system is shown in FIG. **1**. A patient **1** is receiving humidified and pressurised gases through a patient interface **2** connected to a humidified gases transportation pathway or inspiratory conduit **3**. Alternative delivery systems may also be used such as, VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. A nasal mask **2** is illustrated in FIG. **7** but other masks such as oral, full face or nasal cannula may be used. An inspiratory conduit **3** is connected to an outlet **4** of a humidification chamber **5** that contains a volume of water **6**. The inspiratory conduit **3** may contain heating means or heater wires (not shown) that heat the walls of the conduit to reduce condensation of humidified gases within the conduit **3**.

The humidification chamber **5** is preferably formed from a plastics material and preferably has a highly heat conductive base (for example an aluminium base) that is in direct contact with a heater plate **7** of humidifier **8**. The humidifier **8** is provided with control means or an electronic controller **9** that may comprise a microprocessor based controller executing computer software commands stored in associated memory.

The controller **9** preferably receives input from sources such as user input means or a dial **10** through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient **1**. The controller **9** may also receive input from other sources, for example temperature and/or flow velocity sensors **11**, **12**, through a connector **13** and a heater plate temperature sensor **14**. In response to the user set humidity or temperature value input via the dial **10** and the other inputs, the controller **9** determines when (or to what level) to energise the heater plate **7** to heat the water **6** within the humidification chamber **5**. As the volume of the water **6** within the humidification chamber **5** is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber **5** outlet **4** with the flow of gases (for example air) provided from a gases supply means or blower **15** that enters the chamber **5** through an inlet **16**. Exhaled gases from the patient's mouth are passed directly to the ambient surroundings in FIG. **1**.

The blower **15** is provided with variable pressure regulating means or variable speed fan **21** that draws air or other gases through a blower inlet **17**. The speed of the variable speed fan **21** is controlled by an electronic controller **18** (or alternatively the function of the controller **18** may be carried out by the controller **9**) in response to inputs from the controller **9** and a user set predetermined required value (preset value) of pressure or the fan speed via dial **19**.

FIGS. **2** and **3** show a first embodiment of a patient interface of the present invention. This patient interface is a nasal mask **2**. The nasal mask **2** is comprised of a mask base **22** and body **23**. The body **23** is substantially tubular with two nasal pillows **24**, **25** extending from it. The nasal pillows **24**, **25** are preferably frustoconical in shape and in use rest against a patient's nares, to substantially seal the patient's nares. The body **23** has an external lip **28** that frictionally fits in a channel in the mask base **22**.

The body **23** and nasal pillows **24**, **25** of the nasal mask of the present invention are shown in further detail in FIGS. **6** and **7**. The body and pillows are preferably integrally moulded in a substantially flexible plastics material. In the preferred form this material is silicone, but other appropriate materials, such as, rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used.

The nasal pillows **24**, **25** are preferably an elliptical cone and as such are tubular and allow for a passage of gases to flow from the tubing **3** and through the mask body **23**. The pillows **24**, **25** are preferably angled toward one another and each have a preferably elliptical outlet **26**, **27** that may be slightly offset from the centre of each pillow **24**, **25**, as shown in FIG. **6**.

FIGS. **18** and **19***a* show a nasal pillow **24** with an offset outlet in more detail. The pillow **24** has an outer profile **200** and inner profile **201** with respective centre points **202**, **203**. The inner profile **201** (outlet of the nasal pillow **24**) is offset inward, by a horizontal spacing **204** and vertical spacing **205**. Meaning the outlet **201** of the nasal pillow is offset horizontally **204** towards the middle of the nose and vertically **205** towards the user's upper lip. Offsetting the outlet **201** downwards in this manner allows the outlet to be inserted into a user's nostril without the outer profile **200** pushing the user's upper lip. Offsetting the outlet **201** inwards allows the pillow to better seal on the septum of the user's nose in use.

The outlet **201** may also be angled compared to the outer profile **200**. For example in FIG. **18**, there is a horizontal angle difference between the outer profile **200** and outlet **201** shown as **206**. A similar vertical angle difference between the outer profile **200** and outlet **201** is shown as **207**.

With the outer profile and inner profile having different sections or offsets allows the gradient of the connecting surface between the profiles to be changeable. This is shown in the graphs of FIGS. **19***b*, **19***c* and **19***d*. The connecting surface between the inner **201** and outer **200** profiles can have differing gradients, **208**, **209**, **210**. The different gradients **208**, **209**, **210** of the connecting surface are possible due to the difference in offset difference **211**, **212** (horizontal, vertical or angled) between the inner **201** and outer **200** profiles.

There may also be a difference in the rate of change of the gradient (as illustrated in the difference between **208** and **210**). This allows easier insertion of the pillow **24** into a user's nostrils due to more lead in and better sealing that may be achieved due to more ergonomic contouring of the connecting surface that contacts the user's nostril.

Referring back to FIG. **7**, the external lip **28** on the mask body **23** is an area of reduced circumference around the tubular part of the body **23**. A projection **47** may be provided on the lip **28** that fits with a corresponding recess or channel (discussed below) on the mask base **22** to ensure correct assembly of the nasal mask.

The mask base **22** is shown in further detail in FIGS. **4** and **5**. The mask base **22** is a ring or sleeve type attachment. The base **22** is preferably made from a substantially hard (rigid) plastics material, such as polypropylene, polycarbonate or acetyl. However, other appropriate materials may be used. The base **22** has an internal circumferential recessed area or channel **45** on one side and a semi-tubular projection **29** on its other side. When assembling the mask body **23** to the mask base **22** the channel **45** receives the lip **28**. These parts are maintained together by friction fit, however other types of fitting may be provided for, such as a snap or bump fitted part or the body may be over moulded to a clip that causes the fitting to the mask body **23**. In this form the friction fitting of the lip **28** to the recessed area **45** is assisted by elongate projections **49** extending along the central part **50** of the mask base **22**. The projection **47** on the mask body **23** allows for correct fitting or keying of the mask base to the mask body, such that when the lip **28** is fitted into the recessed area **45**, the projection **47**—enters the recess **48** formed in the mask base **22**.

The semi-tubular projection **29** is curved in this embodiment such that a ball jointed connector end **46** such that a connector **30** can be fitted into it. The projection **29** forms a socket for the connector end **46** and the connector end can swivel within the socket. The connector **30** is attached to a tube **31** to allow for gases to be passed to the nasal mask **2**. The tubing **31** may be attached to inspiratory conduit **3** or the tubing **31** may simply be the inspiratory conduit **3**.

In alternative embodiments the projection **29** may not be semi-circular but the inner surface of the base **22** may be curved and form a socket for receiving the connector end **46**.

The base **22** has an extension or partial lip **32** extending beneath the semi-tubular projection (socket) **29**. A slot **33** is created between the socket **29** and extension **32**. The extension and slot is used to fit the mask base **22** to the headgear **21**. In this embodiment the extension **32** is substantially curved to follow the shaped of the projection **29**. However, in other forms the extension may be substantially straight or otherwise shaped.

In use, the nasal mask is assembled with headgear **21**. The headgear **21** in the preferred form is comprised of headgear straps **35**, **36**, **37**, **38** and a substantially curved and elongate member **34**. The member **34** is curved and substantially rigid, or at least more rigid than the headgear straps.

The headgear straps **35**, **36**, **37**, **38** are preferably made from a composite foam layered material, such as Breathop-

rene™. The headgear **21** preferably includes a first strap **35** and a second strap **36**. The first strap **35** extends in use over the forehead or top front area of a patient's head. The second strap **36** extends around the back of the patient's head. The headgear **21** also has side straps **37**, **38** that in use extend down the cheeks of a patient and the ends of the straps terminate in the upper lip area of the patient in use.

Referring to FIG. **2**, the curved and elongate member **34** is comprised of a central section **42** and contoured side arms **41**, **54**. A substantial length of each of the side arms **41**, **54** overlaps and is attached to the side straps **37**, **38**. However, the side straps **37**, **38** only extend partially along the length of the side arms **41**, **54** so as to terminate beneath the cheek or near the upper lip region. As the side straps **37**, **38** are made from a soft foam type material they provide a comfortable fitting of the headgear and curved member **34**, while the substantially rigid side arms **41**, **54** provide rigidity and stability to the headgear **21** and nasal mask **2**. The attachment between the side straps and rigid extension side arms may be made by gluing, sewing or other appropriate fastening.

Preferably the side arms of the curved member **34** are integrally moulded with the central section **42**. The curved member **34** is preferably three dimensionally moulded to a shape to substantially match the cheek contours of a human. The side arms **41**, **54** are preferably of thinner width (cross-section) than the central section **42**. As the side arms **41**, **54** are moulded of a plastics material to be substantially thin they are capable of being bent or adjusted to allow for better and more comfortable fit to a patient. The side arms **41**, **54** may also include weakened or narrow areas **39** to allow for additional bending, moulding or twisting of the arms **41**, **54** to better fit the headgear to individual patients. For example, in the embodiment shown in FIGS. **2** and **3**, the narrowed area **39** corresponds to the cheek bone area of a patient and allows for the side arms **41**, **54** to easier bend or twist to fit the contours of the patients face.

In alternative embodiments the side arms may have weakened areas that are narrower in cross-section to that of the remainder of the side arms. A narrower cross-section area would also provide a weakened area that may be easily manipulated.

In alternative embodiments of the present invention the side straps of the headgear may not extend under and along the length of the curved member but be attached to the distal ends of the straps. This attachment may be by hook and loop material, as is known in the art, or by other attachment methods as known in the art. In this form, the arms of the curved member may have padding underneath them or no padding at all.

Referring to FIG. **3**, the curved elongate member has a central section **42** that in an assembled form supports the mask base and body such that the pillows **24**, **25** rest against the patient's nares. The central section **42** is a half circle that is integrally moulded with the side arms **41**, **54**. The central section **42** has a raised area **43** on its exterior, at the apex of the half circle. The raised area **43** is shaped to receive the mask base **22**. To assemble, a patient merely needs to slide the mask base **22** into the central section **42** such that the raised area **43** fits into the slot **33** on the mask base **22**.

The side arms **41**, **54** of the curved member **34** preferably have varying cross-sectional thickness. The ends of the arms **41**, **54** attached to the central section **42** are thicker over the most curved parts **55**, **56** of the arms, whereas the straighter parts of the arms **57**, **58** have a narrow cross-section. Therefore, the thicker ends **55**, **56** hold their shape better.

In alternative embodiments, the mask base **22** may be formed integrally with the curved member **34**. Therefore, the central section and base would be one and would not be able to be separated from one another.

An example of this is shown in FIGS. **20** to **22**, the eighth embodiment of the patient interface and headgear **300**. Here, the mask base **301** and the curved elongate member **302** are integrally formed, for example, by moulding or the like. The elongate member comprises arms **303**, **304** similar to that described above. Also the mask body **305** has integral nasal pillows **306**, **307** similar to that described above in relation to FIG. **2**.

As can be seen in FIGS. **21** and **22** in this eighth embodiment the headgear straps **308**, **309** do not extend down the arms **303**, **304** as with other embodiments. In this embodiment the headgear straps **308**, **309** attach through recesses **310**, **313** at the end of the arms **303**, **304** extending along the arms are inner pads **311**, **312** that rest against the patients cheekbones in use and provide comfort to the patient's face. The pads **311**, **312** only extend up to near the attachment recesses **309**, **310**. The pads are preferably made from a foam type material, such as the laminated material that the headgear straps are made from. The pads **311**, **312** preferably do not extend beyond the edges of the arms **303**, **304**.

Referring back to FIGS. **2** and **3**, alternatively, the curved member **34** may be formed as two separate pieces. That is, the central section **42** may be formed as two parts with a central split seam, the two left and right halves joined in use. The two left and right parts could either be joined along a seam as described above, with the base **22** slotting into the slot **33** as described above, or alternatively, each of the two left and right arms may be attached one to each side of the base **22**.

Where a "substantially continuous elongate member" or "curved member" is referred to in this specification, it refers to any of the options for the curved member **34** outlined above.

The side arms **41**, **54** may also include a loop **40** or detached section. This is where a section of the side arms **41** is not attached to the strap **38**, **37** lying underneath. Thus the detached section **40** of the side arms forms a loop to which a tubing attachment **44** (such as that shown attached to another strap in FIGS. **2** and **3**) may be looped to the side arms **41**, **54** and the tubing **31** attached to either of the side arms.

The connector **30** in the preferred form is a ball and socket jointed connector to allow for the tubing **31** to swivel in the mask base **22**. The tubing **31** may be attached to any of the headgear straps. However, a tube attachment **44** is shown where the tubing is attached by fasteners, such as hook and loop fastener, to the first strap **35**. In other embodiments the tubing **31** may be attached to either the side straps **37**, **38** or merely allowed to fall freely from the nasal mask **2**.

Although a ball and socket joint, as described above, between the mask base **22** and tubing **31** is preferred other connections may be utilised, such as a flexible piece of silicone, or other appropriate connection. The connection between the base and tubing must be able to be flexed or rotated to allow for the tubing to be moved without causing the dislodgement of the nasal mask **2** from the user's nares.

The mask body **23** may be provided with nasal pillows of various different sizes, such that user's may remove an existing mask body and simply attach a different sized body to the mask base **22**.

Alternative headgear may be used with the patient interface of the present invention, hi particular, alternative headgear is shown in use with the first form of the patient interface (of FIG. **2**) in FIG. **8**. Here the headgear may include an additional strap **53** extending from the cheek region of the side straps **41** and extending behind the user's head. This lower additional strap **53** may also include substantially rigid arms

51 similar to the arms 41 described above. Any number of connecting straps 52 may also be provided between the upper strap 36 and lower strap 53. Again, the arms 51 would provide stability and rigidity to the additional strap 53.

In the embodiment described above, when the patient interface of the first form is in use, the user's face causes the mask base 22 and body 23 to clip with the curved member 34. This is due to the angle of the curved member 34 and fixing of the mask base 22 and body 23 to the curved member 34.

Further, in all forms, the curved member 34 transfers the load of the patient interface away from the user's nose and to the cheek regions of the user.

A second form of the patient interface and headgear of the present invention is shown in FIGS. 9 and 10. In this embodiment a mouthpiece 100 is attached to the substantially tubular mask body 23 substantially below the nasal pillows 24, 25. The mouthpiece 100 is preferably a flap that is fittable within the patient's mouth. A gases pathway extends through the mask body 23 and through the centre of the mouthpiece 100, such that in use a patient or user is supplied with gases via the nasal pillows 24, 25 and the mouthpiece 100. The flap 100 is preferably made from a silicone plastics material but other appropriate materials such as rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used. The flap 100 is preferably integrally moulded with the mask body 23 and nasal pillows 24, 25. In use the flap 100 sits within the user's mouth between the user's teeth and lips.

In this second form the headgear and particularly the curved member 34 is substantially the same as that described in relation to the first embodiment.

A third form of the patient interface and headgear of the present invention is shown in FIG. 11. In this embodiment a mouthpiece as well as a nose blocking device is attachable to the mask base 22. The mouthpiece 110 and nose blocking device 111 are preferably integrally formed. The mouthpiece 110 has an inner vestibular shield 112 that is similar to the flap 100 described above. Therefore the vestibular shield 112 in use sits within the patient's mouth between the patient's teeth and lips and provides an at least partial seal between the user and the shield 112.

A tubular extension 113 extends through the mouthpiece 110 to the mask base 22 from the vestibular shield 112. The extension allows for gases to be passed to the patient from the conduit 31.

The nose blocking device 111 in use rests under the user's nose and blocks the user's nares.

In this third form the headgear and particularly the curved member 34 is substantially the same as that described in relation to the first embodiment.

A fourth embodiment of the patient interface and headgear of the present invention is shown in FIG. 12. In this embodiment a mouthpiece 120, 121 is attachable via a tubular extension 122 to the mask base 22. The mouthpiece is made up of an outer mouthpiece flap 120 and an inner vestibular shield 121. The shield 121 is substantially the same as that described in reference to the third embodiment. The outer mouthpiece flap 120 rests in use outside the user's mouth and substantially seals about the user's mouth. The outer mouthpiece flap 120 and an inner vestibular shield 121 are described in further detail in U.S. Pat. No. 6,679,257, the entire contents of which is herein incorporated by reference.

In the fourth form of the headgear and particularly the curved member 34 is substantially the same as that described in relation to the first embodiment.

A fifth form of the patient interface and headgear of the present invention is shown in FIGS. 13 and 14. This embodiment is very similar to the fourth embodiment except the mouthpiece is simply an outer mouthpiece flap 130. This flap 130 is fittable to the mask base 22 by way of the tubular extension 131. Again, as above, the headgear and particularly the curved member 34 are substantially the same as that described in relation to the first embodiment.

A sixth form of the patient interface and headgear of the present invention is shown in FIG. 15. In this embodiment the patient interface is a full face mask 140 that extends over a user's nose and mouth and under the user's chin in use. The mask 140 has a body 142 made from a substantially rigid plastics material and a cushion 144 made from a substantially soft plastics material. The mask and cushion are preferably similar to that described in more detail in U.S. patent application Ser. No. 11/368,004, the entire contents of which is incorporated herein by reference.

A tubular inlet port 143 is formed in the mask body 142. The tubing 31 is attachable to the port 143 to provide gases to the user wearing the mask.

The headgear is substantially similar to that described in relation to FIG. 2 (the second form); however, the curved member 141 differs. The curved member 141 does not have a mask base similar to that described in the second form in which to attach to. Therefore, the curved member 141 has a central section 145 that curves under the inlet port 143, effectively anchoring on the inlet port. The curved member 141 is moulded in substantially the same manner as described with reference to the second form.

A seventh form of the patient interface and headgear of the present invention is shown in FIGS. 16 and 17. Here, the headgear and curved member is similar to that described above in the sixth embodiment, where the curved member 141 has a central section that curves under and anchors onto an inlet port 151 on a patient interface 150. The patient interface 150 is an integral mouth mask 152 and nasal pillows 153. The mouth mask 152 preferably extends under the user's 155 chin, as shown in FIG. 17.

The interface 150 has a substantially rigid body 154 that has substantially soft cushion 156 attached to it. The cushion 156 is preferably of the type disclosed in U.S. Pat. No. 6,951,218 (the entire contents of which is incorporated herein by reference) having an inner 157 and outer 158 cushions.

Integrally formed in the outer cushion 158 are nasal pillows 153. Preferably two nasal pillows 159, 160 are formed in the cushion 158. These are substantially tubular and carry gases in use from the inside of the interface 150 to the user's 155 nares. The outer cushion 158 and nasal pillows 159, 160 are preferably made from a soft pliable plastics material such as silicone but other appropriate materials such as rubber or KRATON™ may be used.

A similar but slightly different embodiment to that of FIG. 16 is a ninth embodiment of the present invention, as shown in FIG. 23. Here the interface 400 is substantially the same as the interface 150 of FIGS. 16 and 17. The interface 400 has a body 401 with integral nasal pillows 402, 403. The nasal pillows may be integrally formed with the body or separately formed and simply assembled to the body before use. The nasal pillows 402, 403, as above, are substantially tubular and carry gases in use from the inside of the interface 400 to the user's nares. Again, nasal pillows are preferably made from a soft pliable plastics material such as silicone but other appropriate materials such as rubber or KRATON™ may be used.

In this embodiment the body 401 may be made of a more rigid material than the nasal pillows or simply be made from a soft pliable plastics material as are the nasal pillows.

Attached to an inlet 404 of the body 401 is an elongate member 405 similar to that described in any of the embodiments detailed above, but particularly that of FIGS. 20 to 22.

The elongate member **405** has arms **406**, **407** that extend along a user's cheekbones then up towards the user's ears when in use. The arms **406**, **407** are preferably made from a substantially rigid material, preferably a plastics material. For the users comfort each of the arms **406**, **407** have inner pads (only one pad **408** is shown in FIG. **23**) extending along their inner sides, particularly where the arms are incident on the user's face.

The arms **406**, **407** have recesses **409**, **410** at there ends to which headgear straps **411**, **412** are attached. The arms **406**, **407** may also each have optional side hooks (of which only one side hook **413** is shown), again made out of a substantially rigid material, to which additional side headgear straps **414**, **415** may be attached.

At the centre of the elongate member **405** is formed an integral inlet **416** that matches and attaches to the inlet **404** on the body. This integral inlet **416** receives a conduit or tube **417** that is connected in use to a supply of gases. Preferably the tube **417** has a swivelable elbow **418** (for example, a ball joint socket similar to the one described above). Preferably on the elbow **418** are a number of holes **419** that provide an exhaust vent for gases exhaled by the patient in use.

In this ninth embodiment of the patient interface and headgear the interface is a mouth mask and nasal pillows. In alternative forms the patient interface may be a full face mask that is attached to an elongate member and headgear similar in form to those described above and particularly in relation to FIG. **23**.

The invention claimed is:

1. A patient interface comprising:

a mask body comprising a substantially flexible plastics material, the mask body comprising a first nasal pillow and a second nasal pillow, the first nasal pillow and the second nasal pillow being angled toward one another, the first nasal pillow comprising a first generally conical portion and a first generally cylindrical portion, the second nasal pillow comprising a second generally conical portion and a second generally cylindrical portion, the first nasal pillow comprising a first outlet opening and the second nasal pillow comprising a second outlet opening;

the mask body also comprising a mask body inlet opening, the mask body inlet opening being spaced apart form the first outlet opening and the second outlet opening, the mask body inlet opening defined within a generally tubular portion of the mask body;

a mask base comprising a plastics material that is less flexible than the substantially flexible plastics material of the mask body, the mask base comprising a housing that defines a through passage, a proximal portion of the through passage being surrounded by a recess, the recess of the mask base receiving the generally tubular portion of the mask body that defines the mask body inlet opening;

a first side arm removably connected to the mask base and a second side arm removably connected to the mask base, the first side arm being three dimensionally molded and having a varying cross-sectional thickness and the second side arm being three dimensionally molded and having a varying cross-sectional thickness; and

headgear comprising a first side strap and a second side strap, the first side strap and the second side strap comprising a composite foam material, the first side arm overlapping with and secured to the first side strap, the second side arm overlapping with and secured to the second side strap, the first side strap extending only partially along the first side arm, the second side strap extending only partially along the second side arm.

2. A patient interface comprising:

a mask body comprising a molded elastomeric material, the mask body comprising two extending nasal pillows and a lip, the nasal pillows, in use, resting in a substantially sealed manner against corresponding nares of a user;

a ring engaged with the lip of the mask body;

a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane;

an elbow rotatably engaged with the ring, the elbow comprising a wall, a vent being formed in the wall of the elbow, the vent comprising a plurality of holes;

a tube or conduit extending from the elbow; and

a headgear comprising side straps that pass down the cheeks of the user, a top strap connected to the side straps, a back strap extending from at least one of the side straps and the top strap, the headgear further comprising molded side arms extending away from the ring to connect with the side straps, wherein the molded side arms overlap the side straps and the side straps are made from a soft foam material, and wherein the side straps overlap the molded side arms on a portion of the molded side arms that is spaced from the ring, the side straps extending away from the ring along the molded side arms;

the elbow being capable of swiveling in the ring such that the tubing can be attached to the top strap or can fall freely;

in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows;

wherein the ring is configured to connect to only two molded side arms and wherein each of the two molded side arms is configured to connect with a single side strap.

3. A patient interface as claimed in claim **2**, wherein the ring comprises a channel receiving the lip of the mask body.

4. A patient interface as claimed in claim **2**, wherein the elbow is capable of swiveling in the ring such that the tubing can be positioned adjacent to any of the side straps.

5. A patient interface as claimed in claim **2**, wherein the ring comprises a hard plastic material.

6. A patient interface as claimed in claim **2**, wherein the soft foam material is a composite foam material.

7. A patient interface as claimed in claim **2**, wherein the side arm is sewn to the side strap.

8. A patient interface as claimed in claim **2**, wherein the side arm is three dimensionally molded to a shape to substantially match contours of a cheek.

9. A patient interface as claimed in claim **2**, wherein the pillows are angled toward one another.

10. A patient interface as claimed in claim **2**, wherein each pillow comprises an inner profile and an outer profile, the inner profile defining an outlet of the nasal pillow, and the inner profile being offset inward relative to the outer profile.

11. A patient interface as claimed in claim **2**, wherein each pillow comprises an inner profile and an outer profile, the inner profile defining an outlet of the nasal pillow, and the inner profile being offset downward relative to the outer profile, to, in use, be offset toward the user's lip.

12. A patient interface as claimed in claim **2**, wherein the top strap includes a first top strap portion and a second top strap portion, wherein the first top strap portion is adjustably connected to the second top strap portion via a buckle.

13. A patient interface as claimed in claim 2, wherein the back strap includes a first back strap portion and a second back strap portion, wherein the first back strap portion is adjustably connected to the second back strap portion via a buckle.

14. A patient interface as claimed in claim 2, wherein the molded side arms have varying cross-sectional thickness along the lengths of the molded side arms.

15. A patient interface as claimed in claim 2, wherein the molded side arms are connected to the ring portion outside of a volume defined by the mask body.

16. A patient interface as claimed in claim 2, wherein at least one of the molded side arms includes a bifurcated portion.

17. A patient interface as claimed in claim 16, wherein the overlap between the side straps and the molded side arms begins at the bifurcated portion of the molded side arms and continues toward at least one of the back strap and the top strap.

18. A patient interface as claimed in claim 16, wherein a first molded arm portion extends from the ring, and wherein a second molded arm portion and a third molded arm portion extend from the first arm portion toward at least one of the back strap and the top strap.

19. A patient interface as claimed in claim 2, wherein at least a portion of each side strap is glued onto a molded side arm.

20. A patient interface as claimed in claim 2, wherein the mask body further comprises at least one projection configured to mate with a recess of the ring when the ring is engaged with the lip of the mask body.

21. A patient interface as claimed in claim 1 further comprising an elbow releasably and rotatably engaged with the through passage of the mask base and a tube or conduit extending from the elbow.

22. A patient interface as claimed in claim 1, wherein the elbow is capable of swiveling in the mask base such that the tubing can be positioned adjacent to any of the side straps.

23. A patient interface as claimed in claim 1, wherein the first side arm is sewn to the first side strap and the second side arm is sewn to the second side strap.

24. A patient interface as claimed in claim 1, wherein the side arm is three dimensionally molded to a shape to substantially match contours of a cheek.

25. A patient interface as claimed in claim 1, wherein each pillow comprises an inner profile and an outer profile, the inner profile defining an outlet of the nasal pillow, and the inner profile being offset inward relative to the outer profile.

26. A patient interface as claimed in claim 1, wherein each pillow comprises an inner profile and an outer profile, the inner profile defining an outlet of the nasal pillow, and the inner profile being offset downward relative to the outer profile, to, in use, be offset toward the user's lip.

27. A patient interface as claimed in claim 1 further comprising a top strap connected to the first side strap and to the second side strap, wherein the top strap includes a first top strap portion and a second top strap portion, wherein the first top strap portion is adjustably connected to the second top strap portion via a buckle.

28. A patient interface as claimed in claim 1 further comprising a back strap extending from at least one of the first side strap, the second side strap, and the top strap, and wherein the back strap includes a first back strap portion and a second back strap portion, wherein the first back strap portion is adjustably connected to the second back strap portion via a buckle.

29. A patient interface as claimed in claim 1, wherein the first side arm and the second side arm are connected to the mask base outside of a volume defined by the mask body.

30. A patient interface as claimed in claim 1, wherein at least one of the molded side arms includes a bifurcated portion.

31. A patient interface as claimed in claim 30, wherein the overlap between the side straps and the molded side arms begins at the bifurcated portion of the molded side arms and continues toward at least one of the back strap and the top strap.

32. A patient interface as claimed in claim 30, wherein a first molded arm portion extends from the back base, and wherein a second molded arm portion and a third molded arm portion extend from the first arm portion toward at least one of the back strap and the top strap.

33. A patient interface as claimed in claim 1, wherein at least a portion of each side strap is glued onto a molded side arm.

34. A patient interface as claimed in claim 1, wherein the tubular portion of the mask body further comprises at least one projection configured to mate with the recess of the mask base.

35. A patient interface as claimed in claim 2, wherein the ring is configured to releasably connect to the two molded side arms.

36. A patient interface as claimed in claim 2, wherein the ring is integrally formed with at least one of the two molded side arms.

* * * * *

EXHIBIT 3

US008186345B2

(12) **United States Patent**
Payton et al.

(10) **Patent No.: US 8,186,345 B2**
(45) **Date of Patent: May 29, 2012**

(54) **APPARATUS FOR SUPPLYING GASES TO A PATIENT**

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(73) Assignee: **Fisher & Paykel Healthcare Limited**, Auckland (NZ)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 204 days.

(21) Appl. No.: **12/777,370**

(22) Filed: **May 11, 2010**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(30) **Foreign Application Priority Data**

Aug. 20, 2004 (NZ) 534853

(51) **Int. Cl.**
A61M 11/00 (2006.01)

(52) **U.S. Cl.** **128/204.17**; 128/204.21; 261/DIG. 65

(58) **Field of Classification Search** ..... 128/204.17, 128/203.17, 205.23, 202.22, 204.21, 204.22, 128/204.18; 261/19, 131, 142, DIG. 65
See application file for complete search history.

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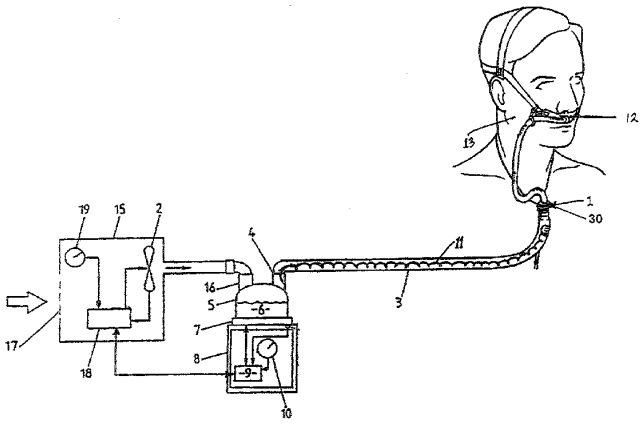
Primary Examiner — Steven Douglas
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

The gases temperature supplied to a patient when the patient is undergoing treatment such as oxygen therapy or positive pressure treatment for conditions such as Obstructive Sleep Apnea (OSA) or Chronic Obstructive Pulmonary Disease (COPD) is often measured for safety and to enable controlling of the humidity delivered to the patient. The invention disclosed is related to measurement of properties, particularly temperature, of gases flowing through a heated tube, supplying gases to a patient, which utilizes the heating wire within the tube.

11 Claims, 4 Drawing Sheets



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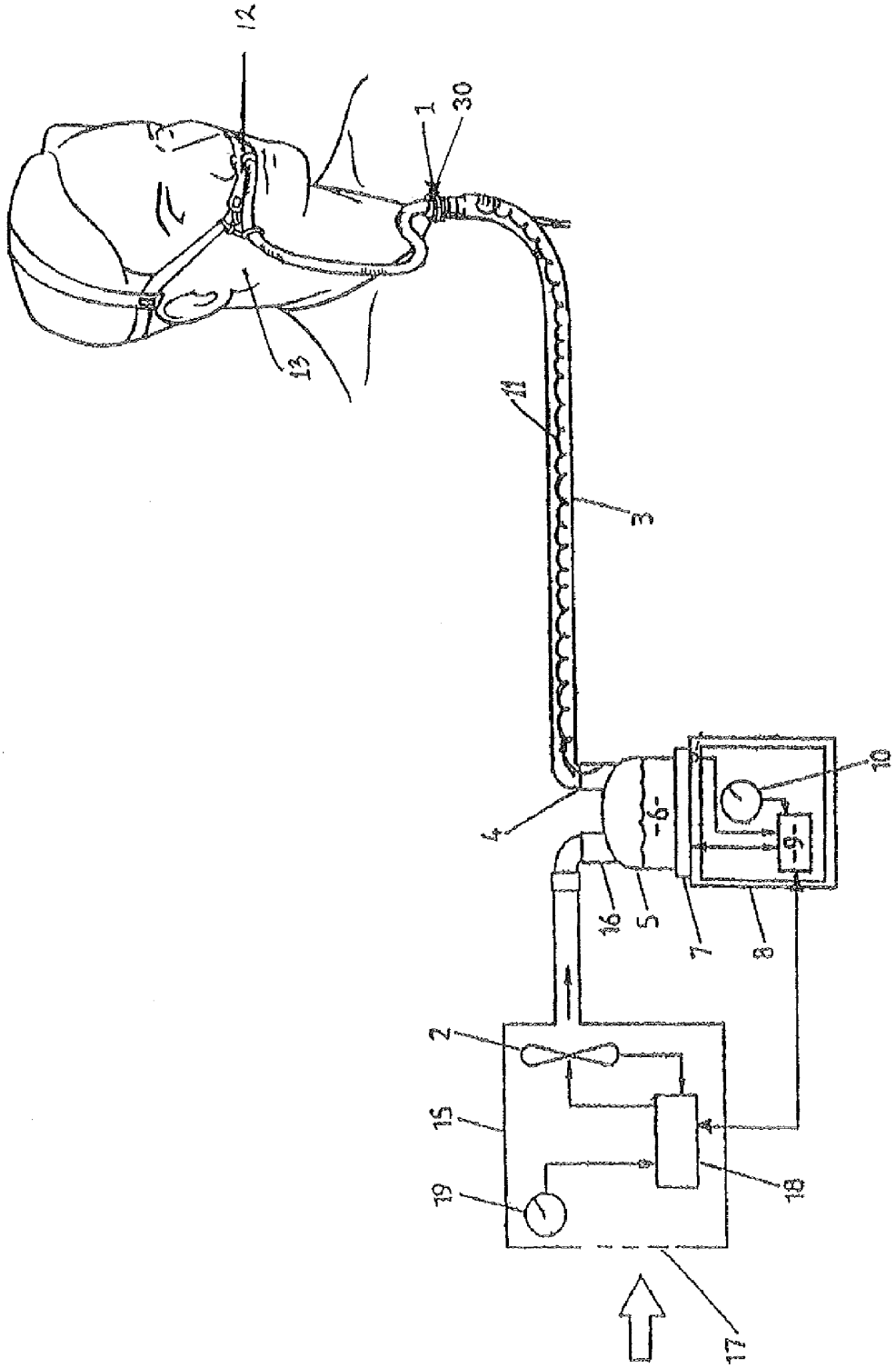

Figure 1

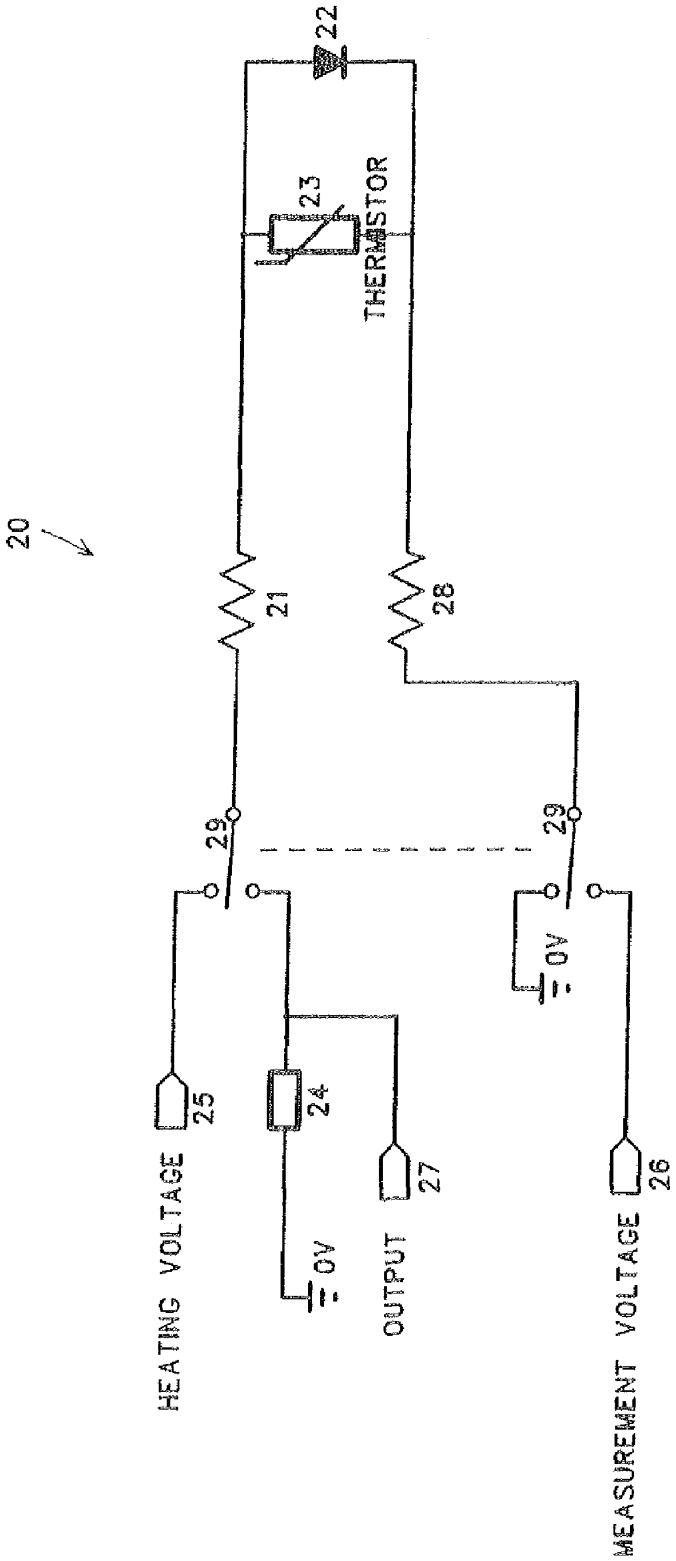
20
22
23
THERMISTOR
21
28
29
29
0V
24
25
26
27
HEATING VOLTAGE
0V
OUTPUT
MEASUREMENT VOLTAGE

Figure 2

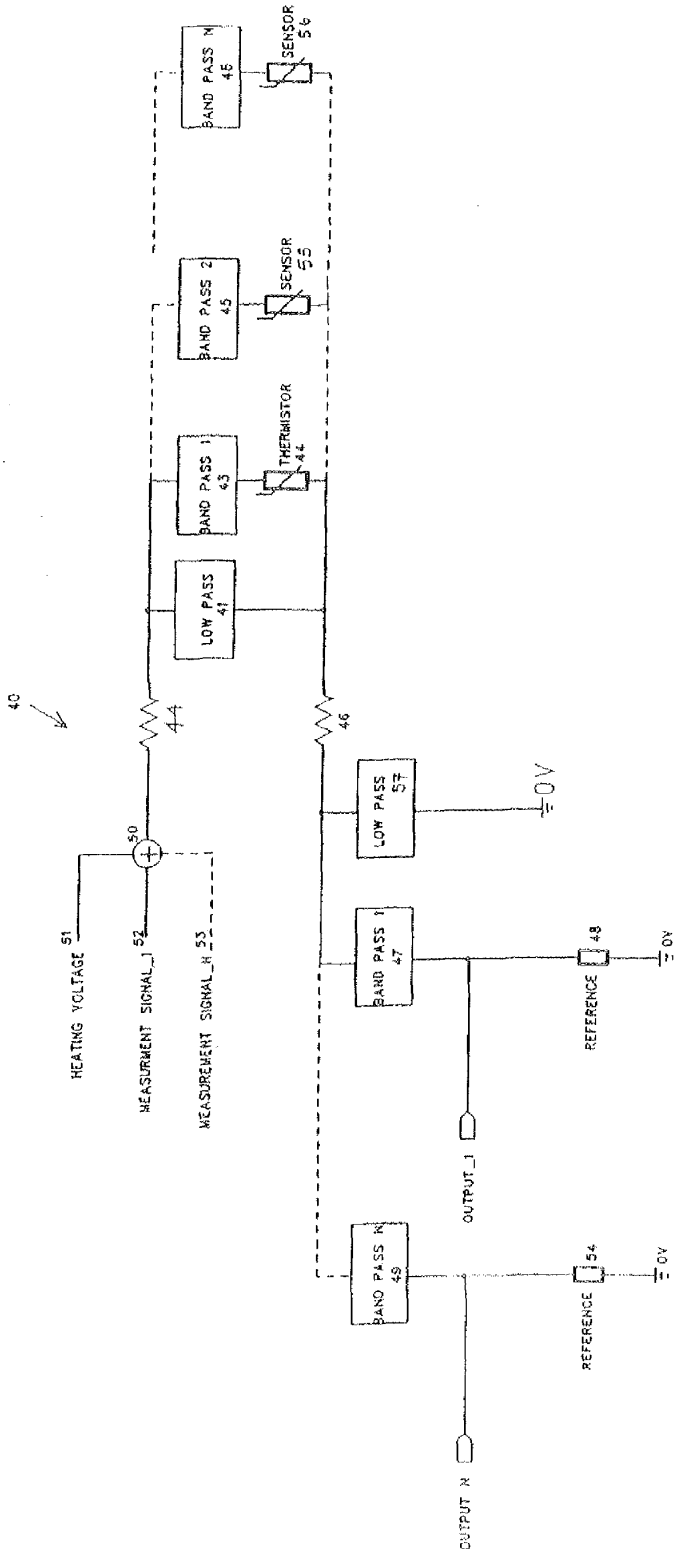
40
HEATING VOLTAGE 51
MEASUREMENT SIGNAL_L 52
MEASUREMENT SIGNAL_H 53
50
44
46
LOW PASS 41
BAND PASS 1 43
THERMISTOR 44
BAND PASS 2 45
SENSOR 55
BAND PASS N 45
SENSOR 56
LOW PASS 57
0V
BAND PASS 1 47
REFERENCE 48
0V
OUTPUT_1
BAND PASS N 49
REFERENCE 54
0V
OUTPUT N

Figure 3

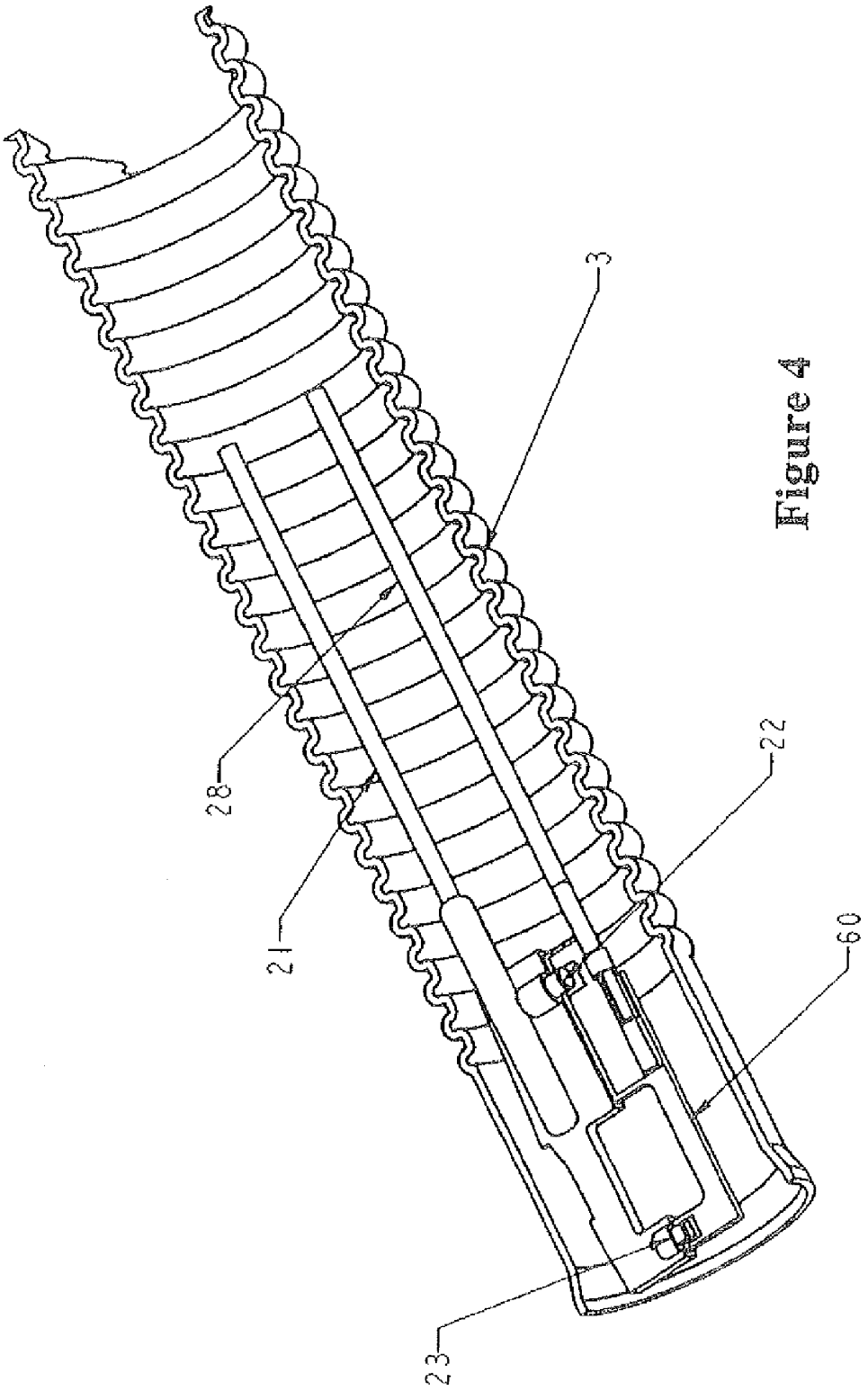

Figure 4

APPARATUS FOR SUPPLYING GASES TO A PATIENT

This application is a divisional application of U.S. patent application Ser. No. 11/572,822 which received a 371 filing date of Oct. 18, 2007, which in turn, is the National Phase filing of PCT/NZ2005/000219, having an International filing date of Aug. 19, 2005, which claims priority of NZ534853 having a filing date of Aug. 20, 2004. All of these are hereby incorporated by reference in their entirety.

TECHNICAL FIELD

This invention relates to an apparatus for supplying breathing gases to a patient.

In particular, the invention relates to an apparatus that can identify the type of conduit attached to it and apply an appropriate control strategy for heating the conduit.

BACKGROUND ART

The gases temperature supplied to a patient when the patient is undergoing treatment such as oxygen therapy or positive pressure treatment for conditions such as Obstructive Sleep Apnea (OSA) or Chronic Obstructive Pulmonary Disease (COPD) is often measured for safety and to enable controlling of the humidity delivered to the patient. Measurement of temperature near the patient is commonly performed using a probe inserted into the breathing tube, such as that of Fisher & Paykel Healthcare Limited, U.S. Pat. No. 6,272,933 and U.S. Pat. No. 6,584,972. Such a temperature probe is connected to the humidifier through a cable that runs external to the breathing circuit. This approach has some drawbacks. In particular, the user must correctly install the temperature probe. If the probe is not correctly installed then the humidification system may malfunction which may increase risk to the patient. Existing end of breathing tube sensors require sensor wires to be run down the outside of the breathing tube. This lowers reliability of the sensors due to the vulnerability of these wires. Alternatively, if these wires are run down the inside of the breathing tube there would be an increase of the resistance to airflow and the hygiene of the breathing circuit would be lowered.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide an improved apparatus for supplying gases to a patient or which will at least provide the industry with a useful choice.

In a first aspect the invention consists in an apparatus for supplying gases to a patient comprising:

- a gases supply,
- a delivery conduit including a heater wire for heating said conduit, wherein said heater wire is located within, around or throughout said conduit and utilized in an electrical circuit including at least one identification element having a characteristic impedance,
- a controller for controlling the heating of the heater wire and wherein said controller is adapted to measure said characteristic impedance of said identification element and identify said delivery conduit based on said characteristic impedance and to apply power to said heater wire based at least in part on the identified conduit.

Preferably said identification element is located at a patient end of said conduit.

Preferably said characteristic impedance is a thermistor resistance range.

Preferably said identification element is a fixed resistor.

Preferably said controller is configured to measure said characteristic impedance and identify said conduit, upon initial connection of said conduit to said apparatus.

Preferably said controller is configured to measure said characteristic impedance and compare it with a plurality of predetermined impedance ranges at ambient temperature in order to identify said conduit type.

Preferably said controller is configured to measure said characteristic impedance and compare it with a plurality of predetermined impedance ranges at ambient temperature in order to identify said conduit type.

In a further aspect the invention consists in a method of identifying a conduit attached to an apparatus comprising

- attaching a conduit comprising a heater wire including an identification element to said apparatus,
- measuring a characteristic impedance of said identification element,
- comparing said measured characteristic impedance with a predetermined impedance value,
- applying power to said heater wire based on said comparison.

Preferably said step of measuring said characteristic impedance and said step of identifying said conduit, is carried out upon initial connection of said conduit to said apparatus.

Preferably said characteristic impedance is compared with a plurality of predetermined impedance ranges, and

- said step of applying power is based an the predetermined range that said measured characteristic impedance is in.

Preferably said characteristic impedance is compared with a plurality of predetermined impedance ranges, and

- said step of applying power is based on the predetermined range that said measured characteristic impedance is in.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

FIG. **1** is an illustration of a respiratory humidifier system that may be used with the method of the present invention of measuring temperature of gases supplied to a patient.

FIG. **2** is a circuit diagram of the electronics enabling the measurement of the temperature of gases to a patient, where the circuit is utilised when the system of the present invention is utilising DC heating and measuring voltages.

FIG. **3** is a circuit diagram of the electronics enabling the measurement of the temperature of gases to a patient, where the circuit is utilised when the system of the present invention is utilising DC or AC voltages for the healing and signal voltages.

FIG. **4** is a cut away of a conduit including a circuit of the present invention on a printed circuit board and residing with the conduit in the area of gases flow.

BEST MODES FOR CARRYING OUT THE INVENTION

The present invention seeks to measure various properties, for example temperature or humidity, at the end of a gas delivery tube or conduit using sensors mounted on a wire, such as a wire used for heating the gases flow through the tube or conduit, where the wire resides within the delivery tube or conduit. A heated tube with a heating wire such as that described in Fisher & Paykel Healthcare Limited U.S. Pat.

No. 6,078,730 or any other similar tube and heating wire could be utilised with the present invention.

Referring to FIG. **1** a ventilation and humidifying system as might be used with the present invention is shown. A patient **13** is receiving humidified and pressurised gases through a nasal cannula **12** connected to a humidified gases transportation pathway or inspiratory conduit **3** that in turn is connected to a humidifier **8** (including humidification chamber **5**) supplied with gases from a blower **15** or other appropriate gases supply means.

The inspiratory conduit **3** is connected to the outlet **4** of the humidification chamber **5** that contains a volume of water **6**. The humidification chamber **5** is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) that is in direct contact with a heater plate **7** of humidifier **8**. The humidifier **8** is provided with control means or an electronic controller **9** that may comprise a microprocessor based controller executing computer software commands stored in associated memory. Gases flowing through the inspiratory conduit **3** are passed to the patient by way of the nasal cannula **12**, but may also be passed to the patient by way of other patient interfaces such as a nasal or full face mask.

The controller **9** receives input from sources such as user input means or dial **10** through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient **13**. In response to the user set humidity or temperature value input via dial **10** and other possible inputs such as internal sensors that sense gases flow or temperature, or by parameters calculated in the controller, controller **9** determines when (or to what level) to energise heater plate **7** to heat the water **6** within humidification chamber **5**. As the volume of water **6** within humidification chamber **5** is heated, water vapour begins to fill the volume of the chamber above the surface of the water and is passed out of the humidification chamber **5** outlet **4** with the flow of gases (for example air) provided from a gases supply means or blower **15** which enters the humidification chamber **5** through inlet **16**.

The blower **15** may be provided with a variable speed pump or fan **2** which draws air or other gases through the blower inlet **17**. The speed of the variable speed pump or fan **2** may be controlled by a further control means or electronic controller **18** which responds either to inputs from controller **9** or to user-set predetermined required values (preset values) of pressure or fan speed, via dial **19**. Alternatively, the function of this controller **18** can be combined with the other controller **9**.

A heating element or wire **11** is preferably provided within, around and throughout the conduit or tubing **3** to help prevent condensation of the humidified gases within the conduit. Such condensation is due to the temperature of the walls of the conduit being close to the ambient temperature, (being the temperature of the surrounding atmosphere) which is usually lower than the temperature of the humidified gases within the conduit. The heater element effectively replaces the energy lost from the gases through conduction and convection during transit through the conduit. Thus the conduit heater element ensures the gases delivered are at an optimal temperature and humidity.

Such a heater wire is commonly driven either with direct current (DC) or alternating current (AC) and in both cases the heating voltage is usually switched on and off to control the power applied to the heating element. In the present invention the heating element **11**, which is most preferably a wire, is used along with an electronic circuit to determine properties of the gases supplied to the patient. The circuit (**20** or **40** in FIGS. **2** and **3**) is preferably connected in series with the heater wire **11**. The circuit may be on a printed circuit board, or wired within a housing that may be a plastic moulding in the gases flow, or a circuit board that is at least partially moulded within the wall of the conduit or tubing **3**. The properties that may be measured include temperature, pressure, gas composition and humidity. Two embodiments of the present invention are described below, one that operates using only a DC heating voltage and the other that can operate with a DC or AC healing voltage.

DC Heating Voltage

FIG. **2** shows a circuit **20** that may be utilised for carrying out the method of measuring temperature of the present invention. When a DC heating voltage **25** is applied to the heater wire the diode **22** conducts and current flows through the heater wire **21**, **28** and the heater wire functions as normal and provides heating to the delivery tube **3**. When the heating voltage **25** is switched off using switch **29**, a measurement voltage **26**, which has opposite polarity to the heating voltage **25** is applied to the heater wire. In this case, the current in the heater wire **21**, **28** does not flow through the diode **22** but flows through the thermistor **23** and through a reference resistor **24**. The voltage across the reference resistor **24** can then be measured at the output **27** and the temperature of the gases determined. The voltage measurement **27** across the reference resistor, **24**, is converted to a temperature using a look up table or an equation to calculate a value for temperature. This is similar to a commonly used technique where the thermistor **23** forms a potential divider with the reference resistor **24**.

More generally, the thermistor may be replaced by an impedance (for example, a resistor and a capacitive sensor) for pressure or humidity measurement. Either the impedance can be measured by measuring the voltage across the reference resistor **24** or the rise-time could be determined by looking at the voltage across the reference resistor **24** in time.

Part of the circuit **20** would be included in the delivery conduit **3** and in particular the diode **22** and thermistor **23** (in parallel with one another) are preferably placed in series with the heater wire **21**, **28** at a point in the heater wire at or near the end **30** (nearest the user **13**, see FIGS. **1**, **2** and **4**) of the delivery tube **3**, for example they may be interconnected on a printed circuit board, overmoulded with plastic for sealing and mounted in the gases stream through the delivery conduit as shown in FIG. **4**. Furthermore, the circuit may be formed by interconnected parts in a housing, for example, a plastic housing, that protrudes from the plastic wall of the delivery tube into the gases flow through the conduit, in order to measure that gases properties. All other parts of the circuit **20** including the reference resistor **24** and the switching circuitry **29** would be included in the control circuitry of the humidifier **8**.

The thermistor's value can be chosen to have different resistance curves with known properties at ambient temperature. The choice of a particular thermistor value for use with the circuit allows identification by the control system of the present invention and matching of that thermistor value with a specific conduit or tubing **3**. Such that different thermistor values can be matched with a particular and appropriate conduit types and upon connection of the conduit to a humidifier or blower device, the control system can identify that thermistor and apply the appropriate control strategy to the heating of the conduit.

AC or DC Heating Voltage

The circuit shown in FIG. **2** is intended to be used when a DC heating voltage is used in conjunction with the heater wire, delivery conduit and system as shown in FIG. **1**. An alternative embodiment of a circuit **40** that would provide

measurement of the gases properties, such as temperature and is suitable for AC and DC voltages, is shown in FIG. **3**. A number of voltage signals **51**, **52**, **53**, which are at different frequencies, are added together at an adder **50**. These signals include at least one heating signal **51** and at least one measuring signal **53**. The combination of these signals passes down the heater wire **44**, creating currents (heating and measuring) in the heater wire **44**. A number of parallel paths are established **41**, **43**, **45** each containing a filter (for example, as shown in FIG. **3**, one low pass filter **41** and three hand pass filters **43**, **45**, **48**) that each pass a different frequency range. These parallel paths (that is, filters, thermistors and/or sensors) are preferably located at the end **30** of the delivery tube **3**, in a similar manner as described in relation to FIG. **2**. The parallel paths allow the heating current to be passed through a different path to the measurement currents. It also allows multiple measurement signals to be passed through the heater wire so that different properties of the gases (e.g. temperature, pressure, humidity, composition) may be measured.

The heating and measurement currents return through the heater wire **46** and can be filtered through a number of measurement filters **47**, **49**, **57** in parallel that pass frequency bands that correspond to the filters, **41**, **43**, **45** located at the end **30** of the tube **3**. The heating current takes a different path than the measurement currents. The measurement currents each take a different path depending on their frequency and this allows each measurement current to be measured by passing it through a reference resistor **48**, **54** or similar. Again a look up table or equation may be used to convert the voltage across the reference resistor **48**, **54** to, for example, a temperature. In the preferred embodiment of the present invention the measurement filters **47**, **49**, **57** would be included in the humidifier **8** control circuitry.

In a further embodiment one or more of the sensing elements **55**, **56** at the end **30** of the delivery tube **3** could be replaced by a fixed impedance to allow identification of the tube so that different control algorithms can be used for different conduits or tubes.

FIG. **4** shows a cutaway view of a conduit **3** with a printed circuit board **60** housing the parts to one of the circuits of the present invention described above with reference to FIG. **2** or **3**. The circuit board **60** is connected to the heating wires **21**, **28** and as such is positioned within the conduit **3**. In this manner, the thermistor **23** included on the board **60** is exposed to the gases flowing through the conduit **3** and can provide measurements of the properties of the gases.

The circuits and method of the present invention can be applied to a number of applications of these technologies for humidification and breathing circuit products. For example, the measurement of the temperature or humidity at the end of the delivery tube (or in a patient interface, for example, nasal cannula or mask) can be used to better control the humidifier, such that a more accurate temperature of gases can be supplied to the patient, providing optimal patient comfort and therapy. Additionally, other gases properties may be measured, such as the gases pressure or gas composition near the patient.

The apparatus of the present invention eliminates the need for external wires for sensing gases properties, as is required by the prior art. Furthermore the apparatus of the present invention only uses two pins or contacts (as opposed to four pins as used in current heated tube implementations). This means the system of the present invention is likely to be more reliable as the contacts/pins are likely to be less prone to breakage. The utilisation of the heater wire for measuring gases properties may also reduce the cost of the breathing tube **3** and associated parts, especially if the breathing tube is to be disposable.

The invention claimed is:

1. An apparatus for supplying gases to a patient comprising:

a gases supply,

a delivery conduit including a heater wire for heating said conduit, wherein said heater wire is located within, around or throughout said conduit and utilized in an electrical circuit including at least one identification element having a characteristic impedance,

a controller for controlling the heating of the heater wire and wherein said controller is adapted to measure said characteristic impedance of said identification element and identify said delivery conduit based on said characteristic impedance and to apply power to said heater wire based at least in part on the identified conduit.

2. An apparatus as claimed in claim **1**, wherein said identification element is located at a patient end of said conduit.

3. An apparatus as claimed in claim **1**, wherein said characteristic impedance is a thermistor resistance range.

4. An apparatus as claimed in claim **1**, wherein said identification element is a fixed resistor.

5. An apparatus as claimed in claim **1**, wherein said controller is configured to measure said characteristic impedance and identify said conduit, upon initial connection of said conduit to said apparatus.

6. An apparatus as claimed in claim **1**, wherein said controller is configured to measure said characteristic impedance and compare it with a plurality of predetermined impedance ranges at ambient temperature in order to identify said conduit type.

7. An apparatus as claimed in claim **5**, wherein said controller is configured to measure said characteristic impedance and compare it with a plurality of predetermined impedance ranges at ambient temperature in order to identify said conduit type.

8. A method of identifying a conduit attached to an apparatus comprising

attaching a conduit comprising a heater wire including an identification element to said apparatus,

measuring a characteristic impedance of said identification element,

comparing said measured characteristic impedance with a predetermined impedance value,

applying power to said heater wire based on said comparison.

9. An apparatus as claimed in claim **8**, wherein said step of measuring said characteristic impedance and said step of identifying said conduit, is carried out upon initial connection of said conduit to said apparatus.

10. An apparatus as claimed in claim **8**, wherein said characteristic impedance is compared with a plurality of predetermined impedance ranges, and

said step of applying power is based on the predetermined range that said measured characteristic impedance is in.

11. An apparatus as claimed in claim **9**, wherein said characteristic impedance is compared with a plurality of predetermined impedance ranges, and

said step of applying power is based on the predetermined range that said measured characteristic impedance is in.

* * * * *

EXHIBIT 4

US008453641B2

(12) **United States Patent**
Payton et al.

(10) **Patent No.: US 8,453,641 B2**
(45) **Date of Patent: Jun. 4, 2013**

(54) **APPARATUS FOR MEASURING PROPERTIES OF GASES SUPPLIED TO A PATIENT**

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(73) Assignee: **Fisher & Paykel Healthcare Limited**, Auckland (NZ)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1157 days.

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(2), (4) Date: **Oct. 18, 2007**

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PCT Pub. Date: **Feb. 23, 2006**

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A61M 11/00 (2006.01)

(52) **U.S. Cl.**
USPC **128/204.17**

(58) **Field of Classification Search**
USPC ..... 128/204.17, 203.17, 205.23, 202.22, 128/204.21, 204.22, 204.18; 261/129, 131, 261/142, DIG. 65
See application file for complete search history.

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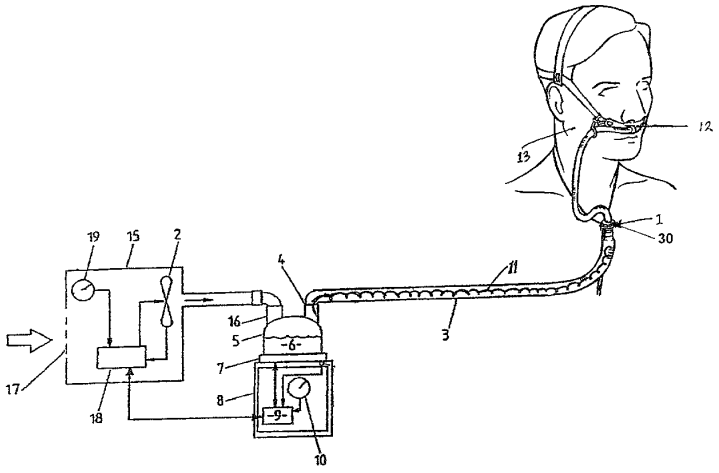
Primary Examiner — Steven Douglas
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

The gases temperature supplied to a patient when the patient is undergoing treatment such as oxygen therapy or positive pressure treatment for conditions such as Obstructive Sleep Apnea (OSA) or Chronic Obstructive Pulmonary Disease (COPD) is often measured for safety and to enable controlling of the humidity delivered to the patient. The invention disclosed is related to measurement of properties, particularly temperature (thermister **23**), of gases flowing through a heated tube (**3**), supplying gases to a patient, which utilizes the heating wire (**21**, **28**) within the tube.

30 Claims, 4 Drawing Sheets



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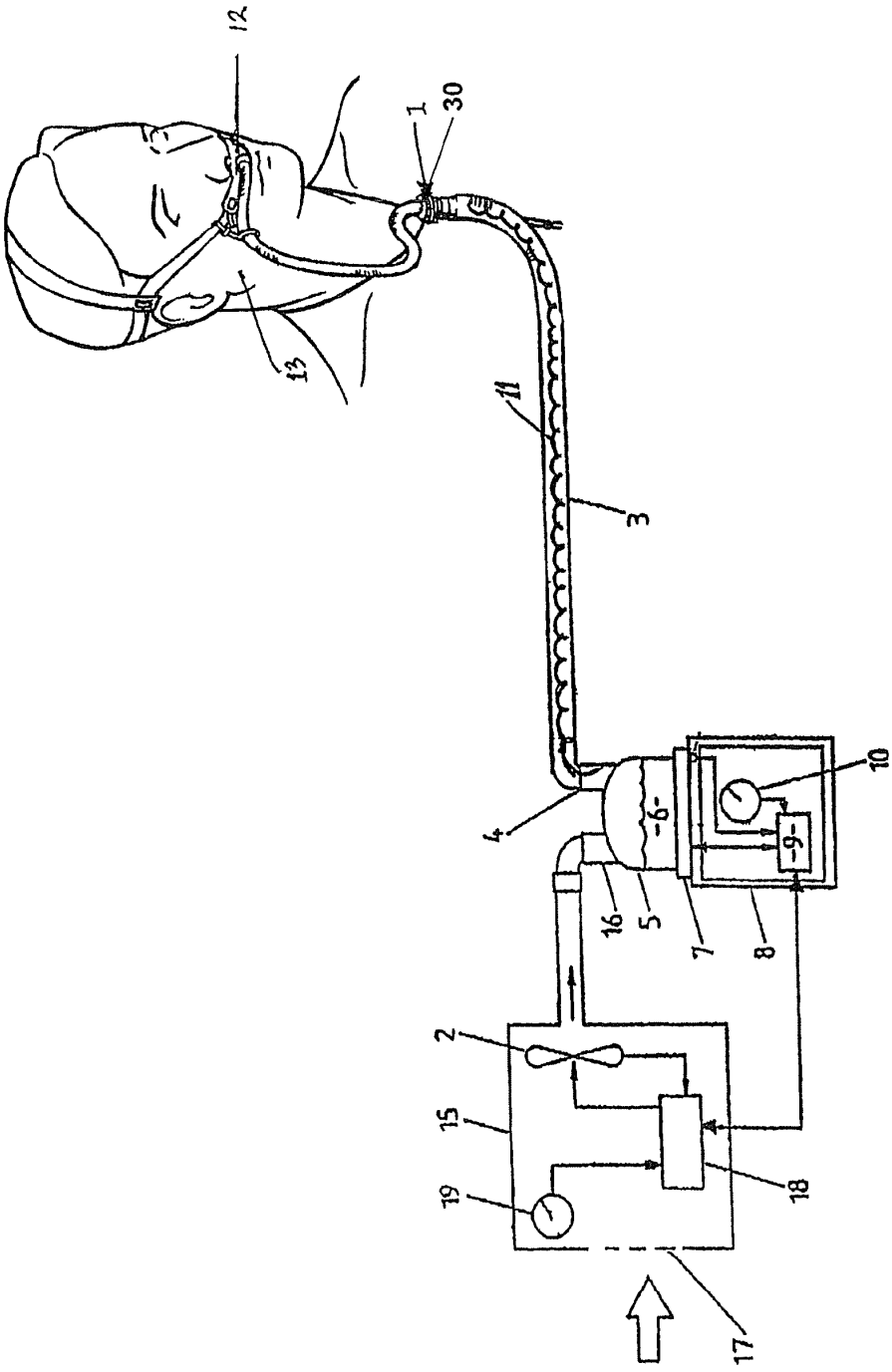

Figure 1

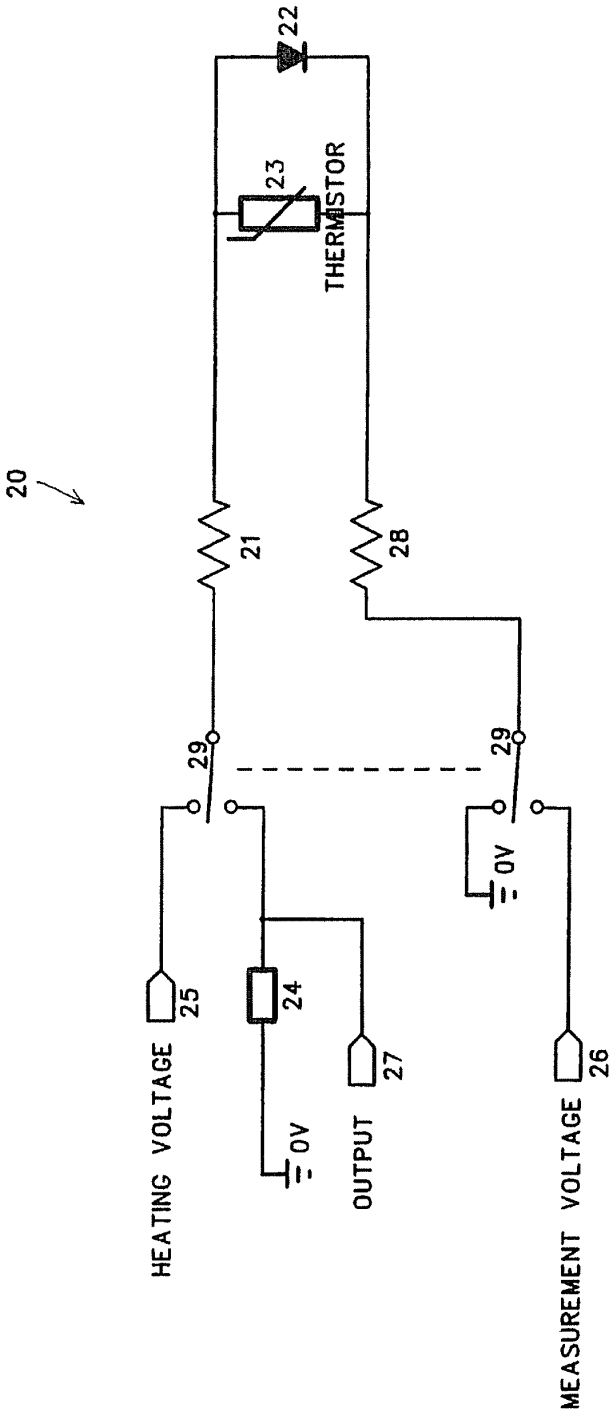
20
22
23
THERMISTOR
21
28
29
29
0V
24
25
27
26
HEATING VOLTAGE
0V
OUTPUT
MEASUREMENT VOLTAGE

Figure 2

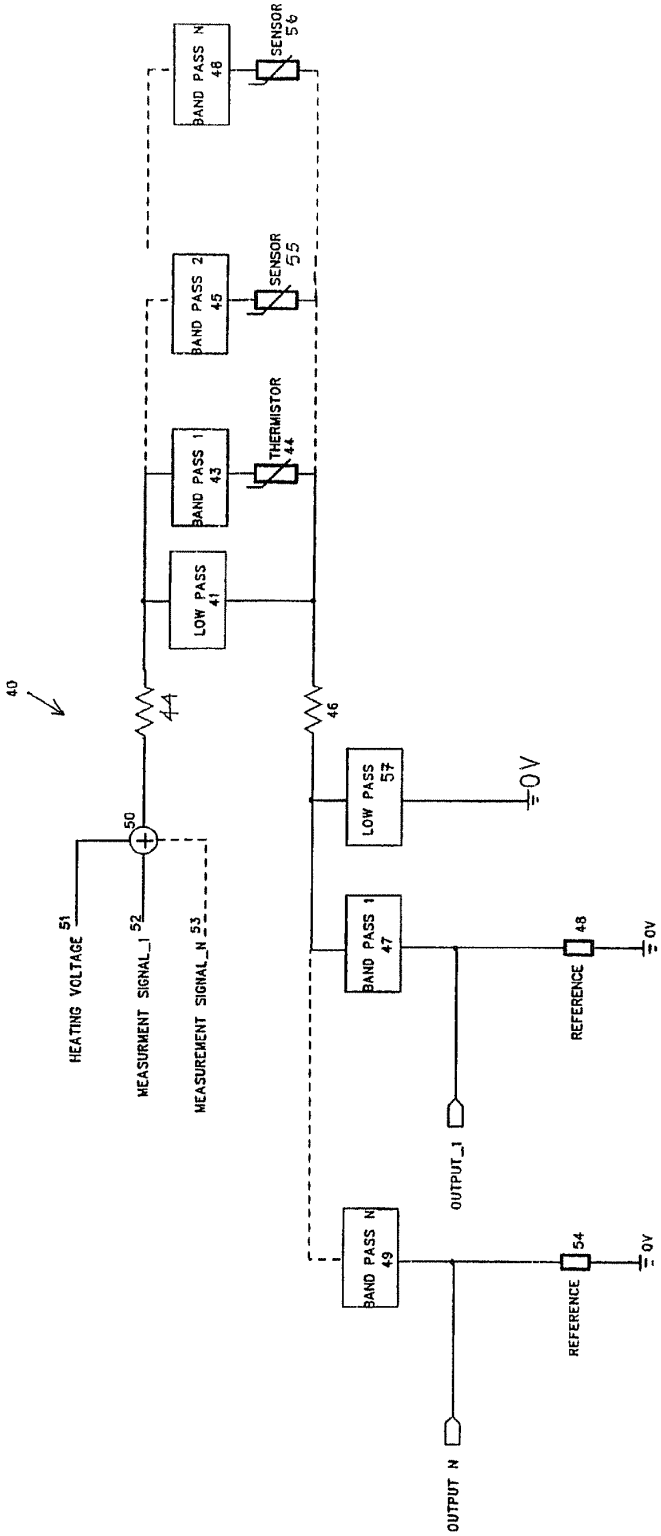
40
HEATING VOLTAGE
51
MEASURMENT SIGNAL_1
52
MEASUREMENT SIGNAL_N
53
50
44
46
LOW PASS 41
BAND PASS 1 43
THERMISTOR 44
BAND PASS 2 45
SENSOR 55
BAND PASS N 48
SENSOR 56
LOW PASS 57
0V
BAND PASS 1 47
REFERENCE
48
0V
OUTPUT_1
BAND PASS N 49
REFERENCE
54
0V
OUTPUT N

Figure 3

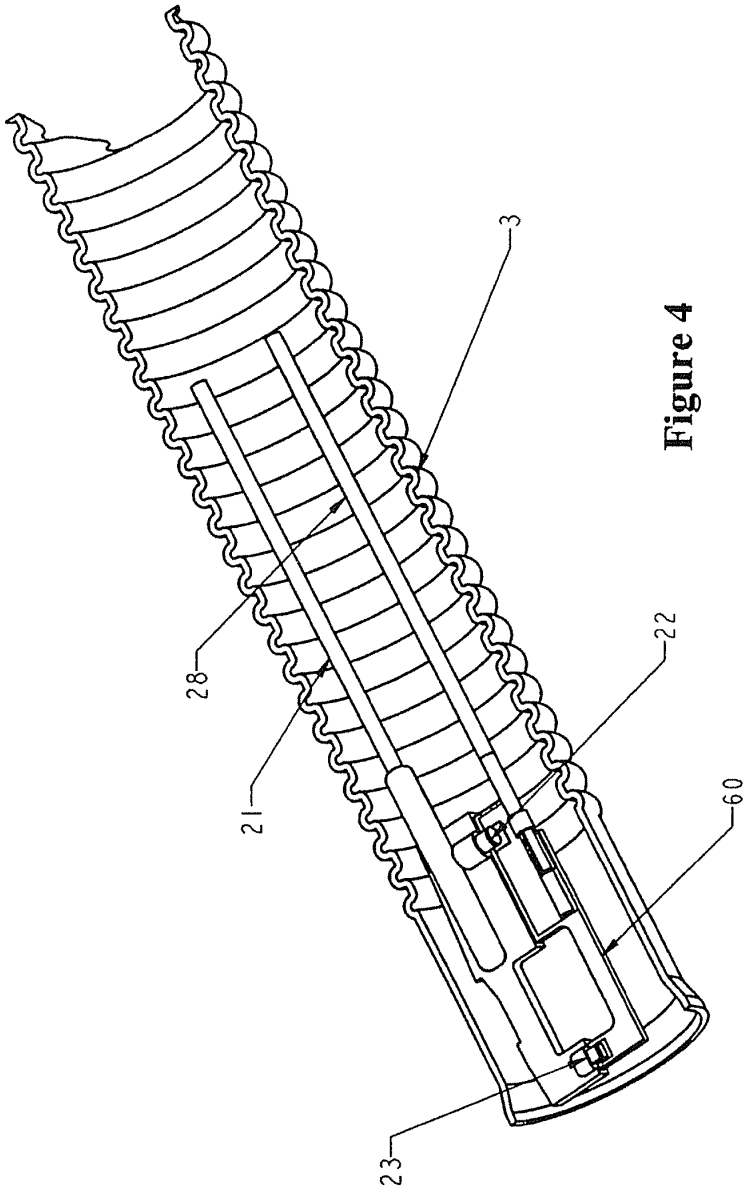

Figure 4

APPARATUS FOR MEASURING PROPERTIES OF GASES SUPPLIED TO A PATIENT

This application is a National Phase filing of PCT/NZ2005/000219, having an International filing date of Aug. 19, 2005, which claims priority of NZ534853 having a filing date of Aug. 20, 2004.

TECHNICAL FIELD

This invention relates to an apparatus for measuring properties, such as temperature and humidity, of gases being supplied to a patient. Humidifiers are commonly controlled by measuring the temperature of gas at two points, adjacent to the output of the humidifier and proximal to the patient. This invention predominantly relates to the measurement of temperature of gas supplied to a patient at a point proximal to the patient.

BACKGROUND ART

The gases temperature supplied to a patient when the patient is undergoing treatment such as oxygen therapy or positive pressure treatment for conditions such as Obstructive Sleep Apnea (OSA) or Chronic Obstructive Pulmonary Disease (COPD) is often measured for safety and to enable controlling of the humidity delivered to the patient. Measurement of temperature near the patient is commonly performed using a probe inserted into the breathing tube, such as that of Fisher & Paykel Healthcare Limited, U.S. Pat. Nos. 6,272,933 and 6,584,972. Such a temperature probe is connected to the humidifier through a cable that runs external to the breathing circuit This approach has some drawbacks. In particular, the user must correctly install the temperature probe. If the probe is not correctly installed then the humidification system may malfunction which may increase risk to the patient. Existing end of breathing tube sensors require sensor wires to be run down the outside of the breathing tube. This lowers reliability of the sensors due to the vulnerability of these wires. Alternatively, if these wires are run down the inside of the breathing tube there would be an increase of the resistance to airflow and the hygiene of the breathing circuit would be lowered.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide a method of measuring properties of gases supplied to a patient that goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

Accordingly in a first aspect the present invention consists in an apparatus for measuring properties of gases being supplied to a patient comprising:

a gases supply,

at least one delivery conduit including a heater wire for heating said conduit,

wherein said heater wire is utilised in an electrical circuit to determine said properties of said gases.

Preferably said electrical circuit is connected in series with said heater wire and provides a measurement or enables a calculation of an indication of at least one of temperature, humidity, pressure and composition of said gases.

Preferably said electrical circuit is mounted and sealed on a printed circuit board that at least partially extends into the gases supplied to said patient through said at least one delivery conduit.

Preferably said electrical circuit is at least partially moulded into the wall of said delivery conduit.

Preferably said electrical circuit includes a sensing means with known properties at ambient temperature such that said sensing means can be matched with said at least one delivery conduit.

Preferably said sensing means is a temperature sensor.

Preferably said electrical circuit includes at least one measuring means in series with said heater wire.

Preferably said at least measuring means is a temperature measuring means.

Preferably said temperature measuring means includes a thermistor and diode in parallel and a reference resistor.

Preferably said thermistor and said diode are located at the end of said delivery conduit near to said patient and said reference resistor is included in said gases supply means.

Preferably said gases supply means includes a device to supply gas flow, such as a blower, and a humidifier to humidify said gases from said blower.

Preferably said gases supply means is a humidifier.

Preferably said electrical circuit includes a gases property measuring means.

Preferably said gases property measuring means includes at least one of a sensor, band pass filter or thermistor and at least one reference resistor.

Preferably said at least one of a sensor, band pass filter or thermistor are located at the end of said delivery conduit near to said patient and said at least one reference resistor and at least one band pass filter is included in said gases supply means.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

FIG. **1** is an illustration of a respiratory humidifier system that may be used with the method of the present invention of measuring temperature of gases supplied to a patient.

FIG. **2** is a circuit diagram of the electronics enabling the measurement of the temperature of gases to a patient, where the circuit is utilised when the system of the present invention is utilising DC heating and measuring voltages.

FIG. **3** is a circuit diagram of the electronics enabling the measurement of the temperature of gases to a patient, where the circuit is utilised when the system of the present invention is utilising DC or AC voltages for the heating and signal voltages.

FIG. **4** is a cut away of a conduit including a circuit of the present invention on a printed circuit board and residing with the conduit in the area of gases flow.

BEST MODES FOR CARRYING OUT THE INVENTION

The present invention seeks to measure various properties, for example temperature or humidity, at the end of a gas delivery tube or conduit using sensors mounted on a wire, such as a wire used for heating the gases flow through the tube or conduit, where the wire resides within the delivery tube or conduit. A heated tube with a heating wire such as that described in Fisher & Paykel Healthcare Limited U.S. Pat. No. 6,078,730 or any other similar tube and heating wire could be utilised with the present invention.

Referring to FIG. **1** a ventilation and humidifying system as might be used with the present invention is shown. A

patient **13** is receiving humidified and pressurised gases through a nasal cannula **12** connected to a humidified gases transportation pathway or inspiratory conduit **3** that in turn is connected to a humidifier **8** (including humidification chamber **5**) supplied with gases from a blower **15** or other appropriate gases supply means.

The inspiratory conduit **3** is connected to the outlet **4** of the humidification chamber **5** that contains a volume of water **6**. The humidification chamber **5** is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) that is in direct contact with a heater plate **7** of humidifier **8**. The humidifier **8** is provided with control means or an electronic controller **9** that may comprise a microprocessor based controller executing computer software commands stored in associated memory. Gases flowing through the inspiratory conduit **3** are passed to the patient by way of the nasal cannula **12**, but may also be passed to the patient by way of other patient interfaces such as a nasal or full face mask.

The controller **9** receives input from sources such as user input means or dial **10** through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient **13**. In response to the user set humidity or temperature value input via dial **10** and other possible inputs such as internal sensors that sense gases flow or temperature, or by parameters calculated in the controller, controller **9** determines when (or to what level) to energize heater plate **7** to heat the water **6** within humidification chamber **5**. As the volume of water **6** within humidification chamber **5** is heated, water vapour begins to fill the volume of the chamber above the surface of the water and is passed out of the humidification chamber **5** outlet **4** with the flow of gases (for example air) provided from a gases supply means or blower **15** which enters the humidification chamber **5** through inlet **16**.

The blower **15** may be provided with a variable speed pump or fan **2** which draws air or other gases through the blower inlet **17**. The speed of the variable speed pump or fan **2** may be controlled by a further control means or electronic controller **18** which responds either to inputs from controller **9** or to user-set predetermined required values (preset values) of pressure or fan speed, via dial **19**. Alternatively, the function of this controller **18** can be combined with the other controller **9**.

A heating element or wire **11** is preferably provided within, around and throughout the conduit or tubing **3** to help prevent condensation of the humidified gases within the conduit. Such condensation is due to the temperature of the walls of the conduit being close to the ambient temperature, (being the temperature of the surrounding atmosphere) which is usually lower than the temperature of the humidified gases within the conduit. The heater element effectively replaces the energy lost from the gases through conduction and convection during transit through the conduit. Thus the conduit heater element ensures the gases delivered are at an optimal temperature and humidity.

Such a heater wire is commonly driven either with direct current (DC) or alternating current (AC) and in both cases the heating voltage is usually switched on and off to control the power applied to the heating element. In the present invention the heating element **11**, which is most preferably a wire, is used along with an electronic circuit to determine properties of the gases supplied to the patient. The circuit (**20** or **40** in FIGS. **2** and **3**) is preferably connected in series with the heater wire **11**. The circuit may be on a printed circuit board, or wired within a housing that may be a plastic moulding in the gases flow, or a circuit board that is at least partially moulded within the wall of the conduit or tubing **3**. The properties that may be measured include temperature, pressure, gas composition and humidity. Two embodiments of the present invention are described below, one that operates using only a DC heating voltage and the other that can operate with a DC or AC heating voltage.

DC Heating Voltage

FIG. **2** shows a circuit **20** that may be utilised for carrying out the method of measuring temperature of the present invention. When a DC heating voltage **25** is applied to the heater wire the diode **22** conducts and current flows through the heater wire **21**, **28** and the heater wire functions as normal and provides heating to the delivery tube **3**. When the heating voltage **25** is switched off using switch **29**, a measurement voltage **26**, which has opposite polarity to the heating voltage **25** is applied to the heater wire. In this case, the current in the heater wire **21**, **28** does not flow through the diode **22** but flows through the thermistor **23** and through a reference resistor **24**. The voltage across the reference resistor **24** can then be measured at the output **27** and the temperature of the gases determined. The voltage measurement **27** across the reference resistor, **24**, is converted to a temperature using a look up table or an equation to calculate a value for temperature. This is similar to a commonly used technique where the thermistor **23** forms a potential divider with the reference resistor **24**.

More generally, the thermistor may be replaced by an impedance (for example, a resistor and a capacitive sensor) for pressure or humidity measurement. Either the impedance can be measured by measuring the voltage across the reference resistor **24** or the rise-time could be determined by looking at the voltage across the reference resistor **24** in time.

Part of the circuit **20** would be included in the delivery conduit **3** and in particular the diode **22** and thermistor **23** (in parallel with one another) are preferably placed in series with the heater wire **21**, **28** at a point in the heater wire at or near the end **30** (nearest the user **13**, see FIGS. **1**, **2** and **4**) of the delivery tube **3**, for example they may be interconnected on a printed circuit board, overmolded with plastic for sealing and mounted in the gases stream through the delivery conduit as shown in FIG. **4**. Furthermore, the circuit may be formed by interconnected parts in a housing, for example, a plastic housing, that protrudes from the plastic wall of the delivery tube into the gases flow through the conduit, in order to measure that gases properties. All other parts of the circuit **20** including the reference resistor **24** and the switching circuitry **29** would be included in the control circuitry of the humidifier **8**.

The thermistor's value can be chosen to have different resistance curves with known properties at ambient temperature. The choice of a particular thermistor value for use with the circuit allows identification by the control system of the present invention and matching of that thermistor value with a specific conduit or tubing **3**. Such that different thermistor values can be matched with a particular and appropriate conduit types and upon connection of the conduit to a humidifier or blower device, the control system can identify that thermistor and apply the appropriate control strategy to the heating of the conduit.

AC or DC Heating Voltage

The circuit shown in FIG. **2** is intended to be used when a DC heating voltage is used in conjunction with the heater wire, delivery conduit and system as shown in FIG. **1**. An alternative embodiment of a circuit **40** that would provide measurement of the gases properties, such as temperature and is suitable for AC and DC voltages, is shown in FIG. **3**. A number of voltage signals **51**, **52**, **53**, which are at different frequencies, are added together at an adder **50**. These signals include at least one heating signal **51** and at least one mea-

suring signal **53**. The combination of these signals passes down the heater wire **44**, creating currents (heating and measuring) in the heater wire **44**. A number of parallel paths are established **41**, **43**, **45** each containing a filter (for example, as shown in FIG. **3**, one low pass filter **41** and three band pass filters **43**, **45**, **48**) that each pass a different frequency range. These parallel paths (that is, filters, thermistors and/or sensors) are preferably located at the end **30** of the delivery tube **3**, in a similar manner as described in relation to FIG. **2**. The parallel paths allow the heating current to be passed through a different path to the measurement currents. It also allows multiple measurement signals to be passed through the heater wire so that different properties of the gases (e.g. temperature, pressure, humidity, composition) may be measured.

The heating and measurement currents return through the heater wire **46** and can be filtered through a number of measurement filters **47**, **49**, **57** in parallel that pass frequency bands that correspond to the filters, **41**, **43**, **45** located at the end **30** of the tube **3**. The heating current takes a different path than the measurement currents. The measurement currents each take a different path depending on their frequency and this allows each measurement current to be measured by passing it through a reference resistor **48**, **54** or similar. Again a look up table or equation may be used to convert the voltage across the reference resistor **48**, **54** to, for example, a temperature. In the preferred embodiment of the present invention the measurement filters **47**, **49**, **57** would be included in the humidifier **8** control circuitry.

In a further embodiment one or more of the sensing elements **55**, **56** at the end **30** of the delivery tube **3** could be replaced by a fixed impedance to allow identification of the tube so that different control algorithms can be used for different conduits or tubes.

FIG. **4** shows a cutaway view of a conduit **3** with a printed circuit board **60** housing the parts to one of the circuits of the present invention described above with reference to FIG. **2** or **3**. The circuit board **60** is connected to the heating wires **21**, **28** and as such is positioned within the conduit **3**. In this manner, the thermistor **23** included on the board **60** is exposed to the gases flowing through the conduit **3** and can provide measurements of the properties of the gases.

The circuits and method of the present invention can be applied to a number of applications of these technologies for humidification and breathing circuit products. For example, the measurement of the temperature or humidity at the end of the delivery tube (or in a patient interface, for example, nasal cannula or mask) can be used to better control the humidifier, such that a more accurate temperature of gases can be supplied to the patient, providing optimal patient comfort and therapy. Additionally, other gases properties may be measured, such as the gases pressure or gas composition near the patient.

The apparatus of the present invention eliminates the need for external wires for sensing gases properties, as is required by the prior art. Furthermore the apparatus of the present invention only uses two pins or contacts (as opposed to four pins as used in current heated tube implementations). This means the system of the present invention is likely to be more reliable as the contacts/pins are likely to be less prone to breakage. The utilisation of the heater wire for measuring gases properties may also reduce the cost of the breathing tube **3** and associated parts, especially if the breathing tube is to be disposable.

The invention claimed is:

1. An apparatus for measuring properties of gases being supplied to a patient comprising:

a gases supply,

at least one delivery conduit including a heater wire for heating said conduit, said conduit having a first end nearest said gases supply and a second end furthest from said gases supply,

wherein said heater wire is located within, around or throughout said conduit, said heater wire extending longitudinally along said conduit from at or near said first end of said conduit to at or near said second end of said conduit, and said heater wire being utilised in an electrical circuit to determine said properties of said gases, said electrical circuit having a first portion and a second portion, said first portion of said electrical circuit being located at or near said first end of said conduit and said second portion of said electrical circuit being located at or near said second end of said conduit, said second portion of said electrical circuit being in electrical communication with said first portion of said electrical circuit through said heater wire such that said first portion and said second portion of said electrical circuit through said heater wire can

feedback to a controller when said properties of said gases vary.

2. An apparatus for measuring properties of gases being supplied to a patient according to claim **1** wherein said electrical circuit is connected in series with said heater wire and provides a measurement or enables a calculation of an indication of at least one of temperature, humidity, pressure and composition of said gases.

3. An apparatus for measuring properties of gases being supplied to a patient according to claim **1** wherein said second portion of said electrical circuit is mounted and sealed on a printed circuit board that at least partially extends into the gases supplied to said patient through said at least one delivery conduit.

4. An apparatus for measuring properties of gases being supplied to a patient according to claim **1** wherein said second portion of said electrical circuit is at least partially moulded into the wall of said delivery conduit.

5. An apparatus for measuring properties of gases being supplied to a patient according to claim **1** wherein said electrical circuit includes a sensor with known properties at ambient temperature such that said sensor can be matched with said at least one delivery conduit.

6. An apparatus for measuring properties of gases being supplied to a patient according to claim **5** wherein said sensor is a temperature sensor.

7. An apparatus for measuring properties of gases being supplied to a patient according to claim **1** wherein said electrical circuit includes at least one gas properties measuring component in series with said heater wire.

8. An apparatus for measuring properties of gases being supplied to a patient according to claim **7** wherein said at least one gas properties measuring circuit is a temperature measuring circuit.

9. An apparatus for measuring properties of gases being supplied to a patient according to claim **8** wherein said temperature measuring circuit includes a thermistor and diode in parallel and a reference resistor.

10. An apparatus for measuring properties of gases being supplied to a patient according to claim **9** wherein said thermistor and said diode are located at the end of said delivery conduit near to said patient and said reference resistor is included in said gases supply.

11. An apparatus for measuring properties of gases being supplied to a patient according to claim **1** wherein said gases supply includes a device to supply gas flow, such as a blower, and a humidifier to humidify said gases from said blower.

12. An apparatus for measuring properties of gases being supplied to a patient according to claim **1** wherein said gases supply is a humidifier.

13. An apparatus for measuring properties of gases being supplied to a patient according to claim **1** wherein said electrical circuit includes a gases property measuring component.

14. An apparatus for measuring properties of gases being supplied to a patient according to claim **13** wherein said gases property measuring component includes at least one of a sensor, band pass filter or thermistor and at least one reference resistor.

15. An apparatus for measuring properties of gases being supplied to a patient according to claim **14** wherein said at least one of a sensor, band pass filter or thermistor are located at the end of said delivery conduit near to said patient and said at least one reference resistor and at least one band pass filter is included in said gases supply.

16. An apparatus for measuring a property of gases being supplied to a patient, the apparatus comprising a conduit having a proximal end and a distal end, the proximal end adapted to connect to a source of breathing gases and a distal end adapted to connect to a patient interface, the conduit comprising a wall defining a lumen, a heating wire extending from a proximal portion of the conduit to a distal portion of the conduit, a gases property sensor being positioned at the distal portion of the conduit, the gases property sensor being connected in series with the heating wire, and the gases property sensor being connected in parallel with a diode such that current flow in one direction can be used for generating heat in the heating wire and current flow in an opposite direction can be used for measuring the property of the breathing gases.

17. The apparatus of claim **16**, wherein a connection to the heating wire, the gases property sensor and the diode are interconnected and sealed at a location exposed to the lumen of the conduit.

18. The apparatus of claim **16**, wherein the gases property sensor comprises a thermistor that is in series with a reference resistor.

19. The apparatus of claim **18**, wherein the gases property sensor comprises impedance for pressure or humidity measurement.

20. The apparatus of claim **18** in combination with a control system, the control system being configured to correlate a specific gases property sensor to a specific conduit such that the control system can apply an appropriate control strategy based upon the identified conduit.

21. An apparatus for measuring properties of gases being supplied to a patient comprising:

a gases supply,

at least one delivery conduit including a heater wire for heating said conduit,

said heater wire being located within, around or throughout said conduit and being utilised in an electrical circuit to determine said properties of said gases, said electrical circuit including a sensing means with known properties at ambient temperature such that said sensing means can be matched with said at least one delivery conduit, and

said electrical circuit providing feedback to a controller when said properties of said gases vary.

22. An apparatus for measuring properties of gases being supplied to a patient according to claim **21** wherein said sensing means is a temperature sensor.

23. An apparatus for measuring properties of gases being supplied to a patient comprising:

a gases supply,

at least one delivery conduit including a heater wire for heating said conduit,

said heater wire being located within, around or throughout said conduit and being utilised in an electrical circuit to determine said properties of said gases, said electrical circuit including at least one gas properties measuring means in series with said heater wire, said at least one gas properties measuring circuit comprising a temperature measuring circuit, said temperature measuring circuit including a thermistor and diode in parallel and a reference resistor, and

said electrical circuit providing feedback to a controller when said properties of said gases vary.

24. An apparatus for measuring properties of gases being supplied to a patient according to claim **23** wherein said thermistor and said diode are located at the end of said delivery conduit near to said patient and said reference resistor is included in said gases supply means.

25. An apparatus for measuring properties of gases being supplied to a patient comprising:

a gases supply,

at least one delivery conduit including a heater wire for heating said conduit,

said heater wire being located within, around or throughout said conduit and utilised in an electrical circuit that includes a gases property measuring means that includes at least one of a sensor, a band bass filter, or a thermistor and at least one reference resistor to determine said properties of said gases, said at least one of a sensor, band pass filter or thermistor are located at the end of said delivery conduit near to said patient and said at least one reference resistor and at least one band pass filter is included in said gases supply means and

said electrical circuit providing feedback to a controller when said properties of said gases vary.

26. An apparatus for measuring properties of gases being supplied to a patient according to claim **1**, wherein said heater wire and said electrical circuit are connected in series.

27. An apparatus for measuring properties of gases being supplied to a patient according to claim **26**, wherein said electrical circuit is positioned on a circuit board or a housing that is positioned in a flow of gases through said conduit.

28. An apparatus for measuring properties of gases being supplied to a patient according to claim **27**, wherein said circuit board is at least partially positioned within a wall of said conduit.

29. An apparatus for measuring properties of gases being supplied to a patient according to claim **26**, wherein a heating voltage is applied to said heater wire to generate heat and said heating voltage is applied and removed, said circuit being electrical powered when said heating voltage is removed.

30. An apparatus for measuring properties of gases being supplied to a patient according to claim **26**, wherein a heating signal and a measurement signal can be passed along said heater wire to create a heating current and a measurement current in said heater wire, said measurement current communicating with said electrical circuit.

* * * * *

EXHIBIT 5

US009265902B2

(12) **United States Patent**
Payton et al.

(10) **Patent No.: US 9,265,902 B2**
(45) **Date of Patent: *Feb. 23, 2016**

(54) **APPARATUS FOR MEASURING PROPERTIES OF GASES SUPPLIED TO A PATIENT**

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(72) Inventors: **Matthew Jon Payton**, Auckland (NZ); **Kevin Peter O'Donnell**, Auckland (NZ); **Andrew Baden Clark**, Auckland (NZ); **Christopher Simon James Quill**, Auckland (NZ); **Peter Geoffrey Hawkins**, Auckland (NZ)

(73) Assignee: **Fisher & Paykel Healthcare Limited**, Auckland (NZ)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 244 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/908,952**

(22) Filed: **Jun. 3, 2013**

(65) **Prior Publication Data**

US 2013/0306075 A1 Nov. 21, 2013

Related U.S. Application Data

(63) Continuation of application No. 11/572,822, filed as application No. PCT/NZ2005/000219 on Aug. 19, 2005, now Pat. No. 8,453,641.

(30) **Foreign Application Priority Data**

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A61M 11/00 (2006.01)
A61M 16/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 16/00*** (2013.01); ***A61M 16/1075*** (2013.01); ***A61M 16/1095*** (2014.02); ***A61M 16/16*** (2013.01); ***A61M 16/161*** (2014.02); *A61M 2016/102* (2013.01); *Y10S 261/65* (2013.01)

(58) **Field of Classification Search**
CPC A61M 2016/0027; A61M 16/0051; A61M 16/0066; A61M 16/0816; A61M 2016/0036; A61M 16/00; A61M 16/1075; A61M 16/16; A61M 2016/102; A61M 16/1095; A61M 16/161; Y10S 261/65
USPC ..... 128/204.21, 204.22, 204.18; 261/129, 261/131, 142, DIG. 65
See application file for complete search history.

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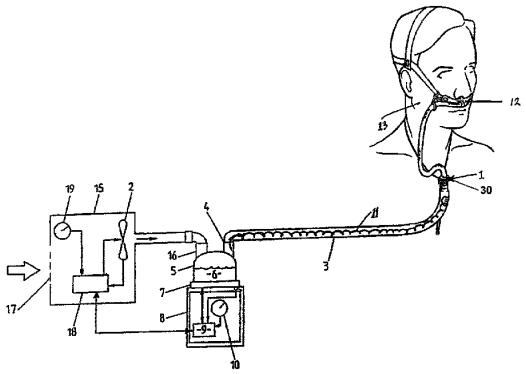
Primary Examiner — Steven Douglas
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

The gases temperature supplied to a patient when the patient is undergoing treatment such as oxygen therapy or positive pressure treatment for conditions such as Obstructive Sleep Apnea (OSA) or Chronic Obstructive Pulmonary Disease (COPD) is often measured for safety and to enable controlling of the humidity delivered to the patient. The apparatus is related to measurement of properties, particularly temperature (thermister **23**), of gases flowing through a heated tube (**3**), supplying gases to a patient, which utilizes the heating wire (**21**, **28**) within the tube.

33 Claims, 4 Drawing Sheets



(51) **Int. Cl.**
A61M 16/10 (2006.01)
A61M 16/16 (2006.01)

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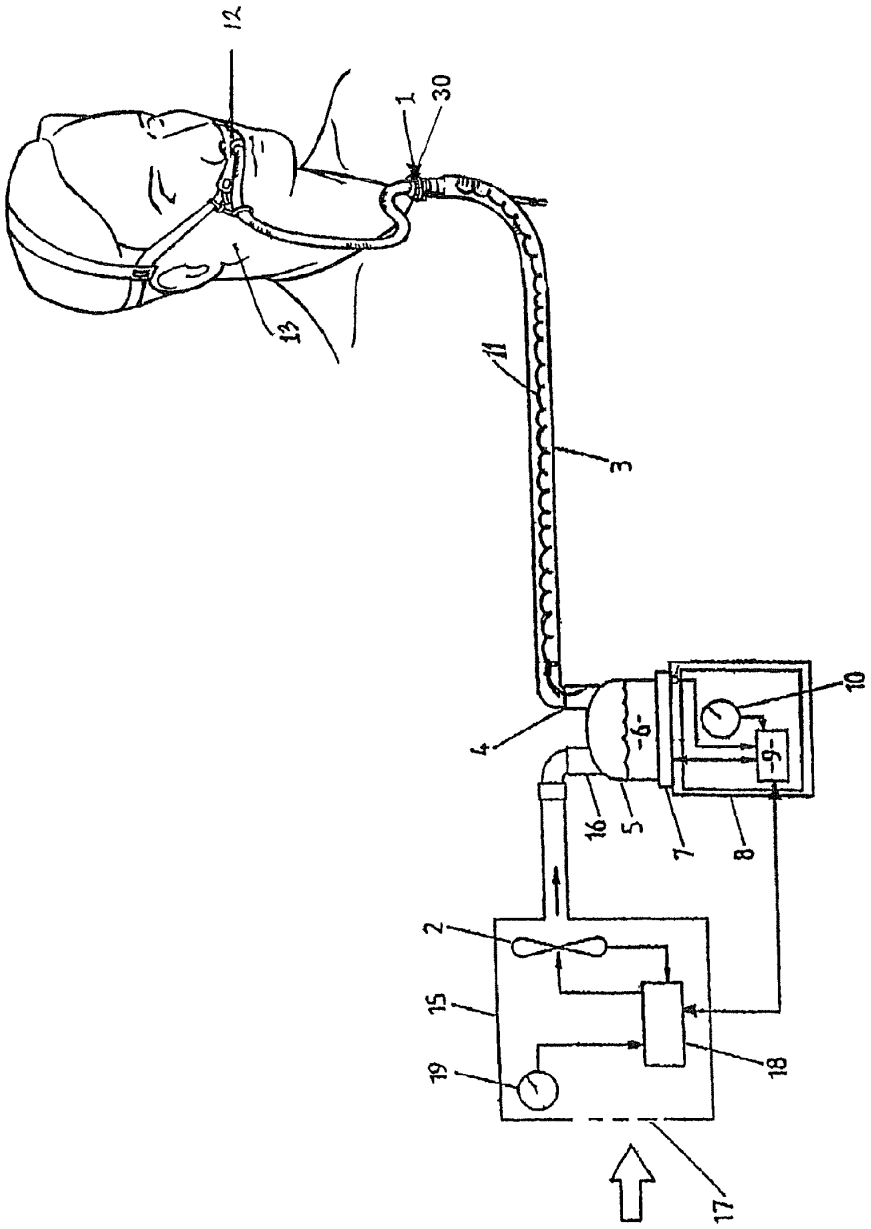
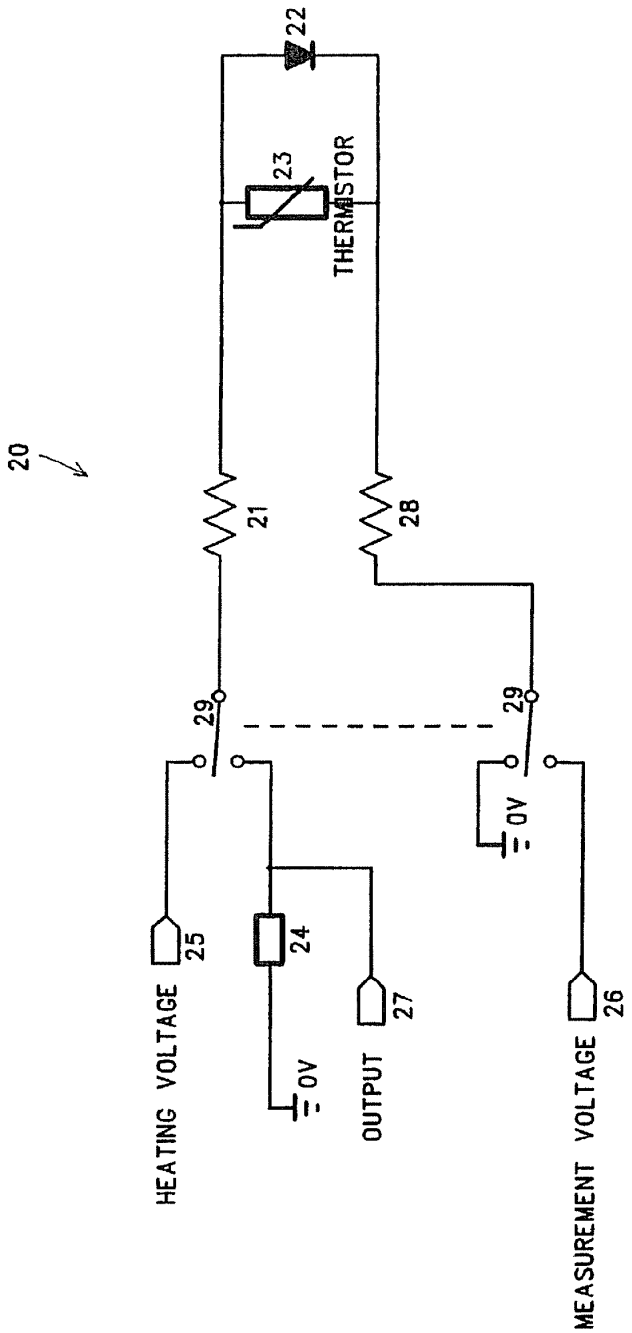


Figure 1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22
23
THERMISTOR
21
28
29
29
0V
24
25
27
26
HEATING VOLTAGE
0V
OUTPUT
MEASUREMENT VOLTAGE

Figure 2

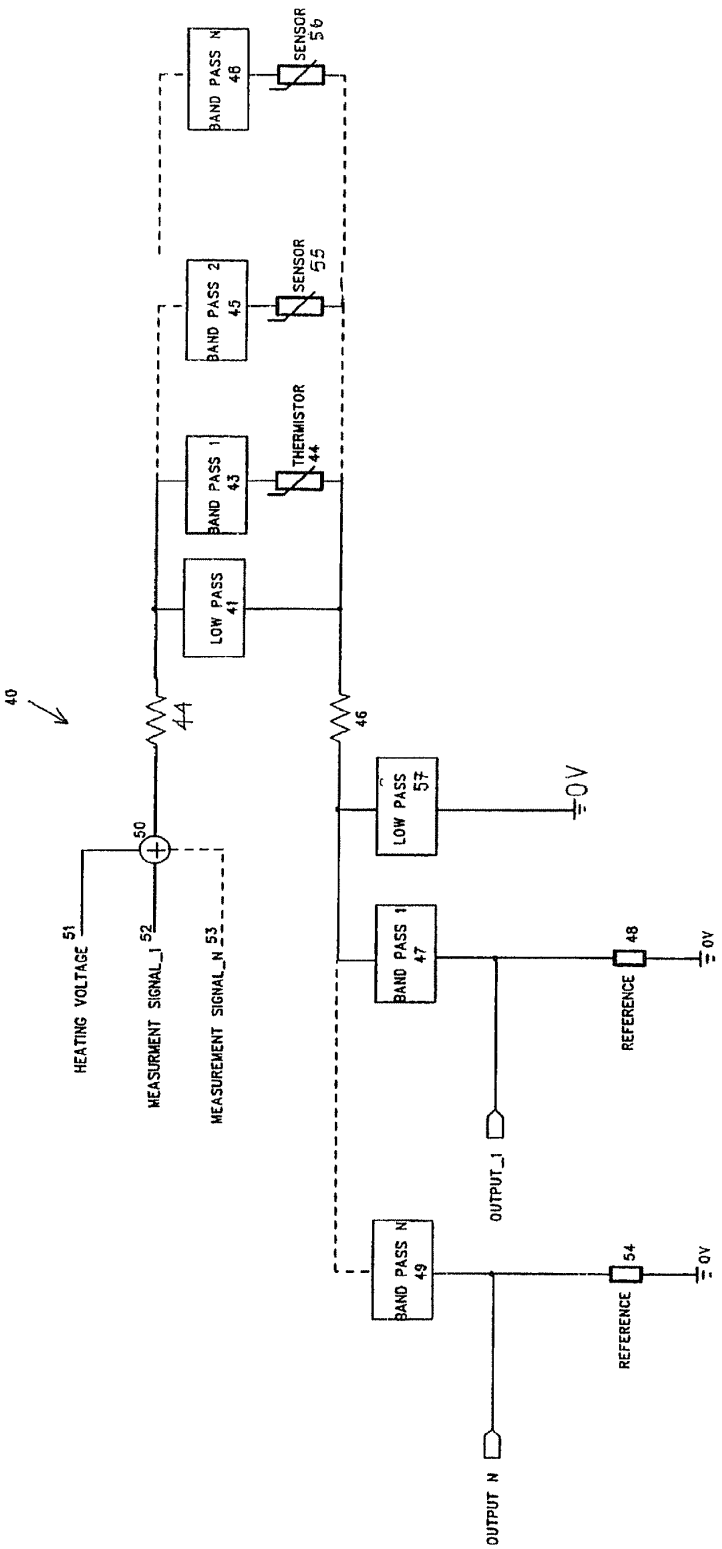
40
HEATING VOLTAGE
51
MEASURMENT SIGNAL_1
52
MEASUREMENT SIGNAL_N
53
50
44
46
LOW PASS
41
BAND PASS 1
43
THERMISTOR
44
BAND PASS 2
45
SENSOR
55
BAND PASS N
46
SENSOR
56
LOW PASS
57
0V
BAND PASS 1
47
REFERENCE
48
0V
OUTPUT_1
BAND PASS N
49
54
REFERENCE
0V
OUTPUT N

Figure 3

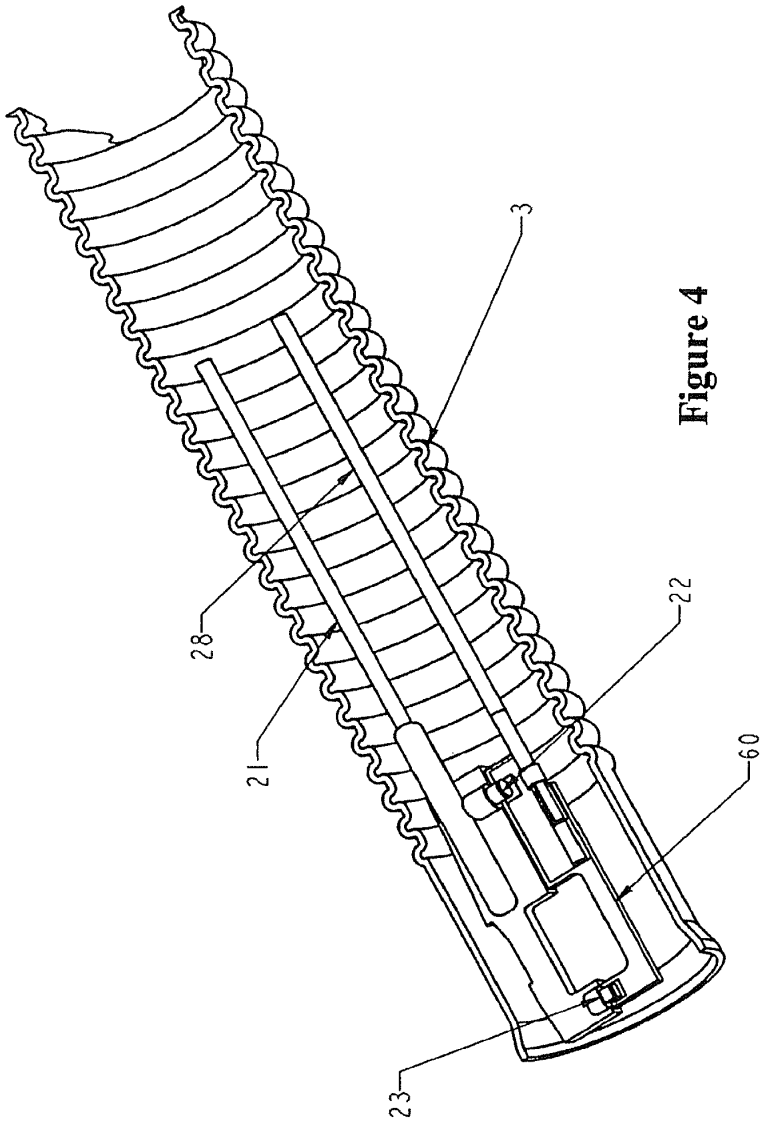

Figure 4

APPARATUS FOR MEASURING PROPERTIES OF GASES SUPPLIED TO A PATIENT

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.

This application is a continuation of U.S. patent application Ser. No. 11/572,822, filed Oct. 18, 2007, now U.S. Pat. No. 8,453,641, issued Jun. 4, 2013, which is a National Phase filing of PCT/NZ2005/000219, having an International filing date of Aug. 19, 2005, which claims priority of NZ534853 having a filing date of Aug. 20, 2004.

BACKGROUND

1. Field

This invention relates to an apparatus for measuring properties, such as temperature and humidity, of gases being supplied to a patient. Humidifiers are commonly controlled by measuring the temperature of gas at two points, adjacent to the output of the humidifier and proximal to the patient. This invention predominantly relates to the measurement of temperature of gas supplied to a patient at a point proximal to the patient.

2. Description of the Related Art

The gases temperature supplied to a patient when the patient is undergoing treatment such as oxygen therapy or positive pressure treatment for conditions such as Obstructive Sleep Apnea (OSA) or Chronic Obstructive Pulmonary Disease (COPD) is often measured for safety and to enable controlling of the humidity delivered to the patient. Measurement of temperature near the patient is commonly performed using a probe inserted into the breathing tube, such as that of Fisher & Paykel Healthcare Limited, U.S. Pat. Nos. 6,272,933 and 6,584,972. Such a temperature probe is connected to the humidifier through a cable that runs external to the breathing circuit This approach has some drawbacks. In particular, the user must correctly install the temperature probe. If the probe is not correctly installed then the humidification system may malfunction which may increase risk to the patient. Existing end of breathing tube sensors require sensor wires to be run down the outside of the breathing tube. This lowers reliability of the sensors due to the vulnerability of these wires. Alternatively, if these wires are run down the inside of the breathing tube there would be an increase of the resistance to airflow and the hygiene of the breathing circuit would be lowered.

SUMMARY

It is an object of the present invention to provide a method of measuring properties of gases supplied to a patient that goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

Accordingly in a first aspect the present invention consists in an apparatus for measuring properties of gases being supplied to a patient comprising:

a gases supply,

at least one delivery conduit including a heater wire for heating said conduit,

wherein said heater wire is utilised in an electrical circuit to determine said properties of said gases.

Preferably said electrical circuit is connected in series with said heater wire and provides a measurement or enables a calculation of an indication of at least one of temperature, humidity, pressure and composition of said gases.

Preferably said electrical circuit is mounted and sealed on a printed circuit board that at least partially extends into the gases supplied to said patient through said at least one delivery conduit.

Preferably said electrical circuit is at least partially moulded into the wall of said delivery conduit.

Preferably said electrical circuit includes a sensing means with known properties at ambient temperature such that said sensing means can be matched with said at least one delivery conduit.

Preferably said sensing means is a temperature sensor.

Preferably said electrical circuit includes at least one measuring means in series with said heater wire.

Preferably said at least measuring means is a temperature measuring means.

Preferably said temperature measuring means includes a thermistor and diode in parallel and a reference resistor.

Preferably said thermistor and said diode are located at the end of said delivery conduit near to said patient and said reference resistor is included in said gases supply means.

Preferably said gases supply means includes a device to supply gas flow, such as a blower, and a humidifier to humidify said gases from said blower.

Preferably said gases supply means is a humidifier.

Preferably said electrical circuit includes a gases property measuring means.

Preferably said gases property measuring means includes at least one of a sensor, band pass filter or thermistor and at least one reference resistor.

Preferably said at least one of a sensor, band pass filter or thermistor are located at the end of said delivery conduit near to said patient and said at least one reference resistor and at least one band pass filter is included in said gases supply means.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

FIG. **1** is an illustration of a respiratory humidifier system that may be used with the method of the present invention of measuring temperature of gases supplied to a patient.

FIG. **2** is a circuit diagram of the electronics enabling the measurement of the temperature of gases to a patient, where the circuit is utilised when the system of the present invention is utilising DC heating and measuring voltages.

FIG. **3** is a circuit diagram of the electronics enabling the measurement of the temperature of gases to a patient, where the circuit is utilised when the system of the present invention is utilising DC or AC voltages for the heating and signal voltages.

FIG. **4** is a cut away of a conduit including a circuit of the present invention on a printed circuit board and residing with the conduit in the area of gases flow.

DETAILED DESCRIPTION

The present invention seeks to measure various properties, for example temperature or humidity, at the end of a gas delivery tube or conduit using sensors mounted on a wire, such as a wire used for heating the gases flow through the tube

or conduit, where the wire resides within the delivery tube or conduit. A heated tube with a heating wire such as that described in Fisher & Paykel Healthcare Limited U.S. Pat. No. 6,078,730 or any other similar tube and heating wire could be utilised with the present invention.

Referring to FIG. **1** a ventilation and humidifying system as might be used with the present invention is shown. A patient **13** is receiving humidified and pressurised gases through a nasal cannula **12** connected to a humidified gases transportation pathway or inspiratory conduit **3** that in turn is connected to a humidifier **8** (including humidification chamber **5**) supplied with gases from a blower **15** or other appropriate gases supply means.

The inspiratory conduit **3** is connected to the outlet **4** of the humidification chamber **5** that contains a volume of water **6**. The humidification chamber **5** is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) that is in direct contact with a heater plate **7** of humidifier **8**. The humidifier **8** is provided with control means or an electronic controller **9** that may comprise a microprocessor based controller executing computer software commands stored in associated memory. Gases flowing through the inspiratory conduit **3** are passed to the patient by way of the nasal cannula **12**, but may also be passed to the patient by way of other patient interfaces such as a nasal or full face mask.

The controller **9** receives input from sources such as user input means or dial **10** through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient **13**. In response to the user set humidity or temperature value input via dial **10** and other possible inputs such as internal sensors that sense gases flow or temperature, or by parameters calculated in the controller, controller **9** determines when (or to what level) to energise heater plate **7** to heat the water **6** within humidification chamber **5**. As the volume of water **6** within humidification chamber **5** is heated, water vapour begins to fill the volume of the chamber above the surface of the water and is passed out of the humidification chamber **5** outlet **4** with the flow of gases (for example air) provided from a gases supply means or blower **15** which enters the humidification chamber **5** through inlet **16**.

The blower **15** may be provided with a variable speed pump or fan **2** which draws air or other gases through the blower inlet **17**. The speed of the variable speed pump or fan **2** may be controlled by a further control means or electronic controller **18** which responds either to inputs from controller **9** or to user-set predetermined required values (preset values) of pressure or fan speed, via dial **19**. Alternatively, the function of this controller **18** can be combined with the other controller **9**.

A heating element or wire **11** is preferably provided within, around and throughout the conduit or tubing **3** to help prevent condensation of the humidified gases within the conduit. Such condensation is due to the temperature of the walls of the conduit being close to the ambient temperature, (being the temperature of the surrounding atmosphere) which is usually lower than the temperature of the humidified gases within the conduit. The heater element effectively replaces the energy lost from the gases through conduction and convection during transit through the conduit. Thus the conduit heater element ensures the gases delivered are at an optimal temperature and humidity.

Such a heater wire is commonly driven either with direct current (DC) or alternating current (AC) and in both cases the heating voltage is usually switched on and off to control the power applied to the heating element. In the present invention the heating element **11**, which is most preferably a wire, is used along with an electronic circuit to determine properties of the gases supplied to the patient. The circuit (**20** or **40** in FIGS. **2** and **3**) is preferably connected in series with the heater wire **11**. The circuit may be on a printed circuit board, or wired within a housing that may be a plastic moulding in the gases flow, or a circuit board that is at least partially moulded within the wall of the conduit or tubing **3**. The properties that may be measured include temperature, pressure, gas composition and humidity. Two embodiments of the present invention are described below, one that operates using only a DC heating voltage and the other that can operate with a DC or AC heating voltage.

DC Heating Voltage

FIG. **2** shows a circuit **20** that may be utilised for carrying out the method of measuring temperature of the present invention. When a DC heating voltage **25** is applied to the heater wire the diode **22** conducts and current flows through the heater wire **21**, **28** and the heater wire functions as normal and provides heating to the delivery tube **3**. When the heating voltage **25** is switched off using switch **29**, a measurement voltage **26**, which has opposite polarity to the heating voltage **25** is applied to the heater wire. In this case, the current in the heater wire **21**, **28** does not flow through the diode **22** but flows through the thermistor **23** and through a reference resistor **24**. The voltage across the reference resistor **24** can then be measured at the output **27** and the temperature of the gases determined. The voltage measurement **27** across the reference resistor, **24**, is converted to a temperature using a look up table or an equation to calculate a value for temperature. This is similar to a commonly used technique where the thermistor **23** forms a potential divider with the reference resistor **24**.

More generally, the thermistor may be replaced by an impedance (for example, a resistor and a capacitive sensor) for pressure or humidity measurement. Either the impedance can be measured by measuring the voltage across the reference resistor **24** or the rise-time could be determined by looking at the voltage across the reference resistor **24** in time.

Part of the circuit **20** would be included in the delivery conduit **3** and in particular the diode **22** and thermistor **23** (in parallel with one another) are preferably placed in series with the heater wire **21**, **28** at a point in the heater wire at or near the end **30** (nearest the user **13**, see FIGS. **1**, **2** and **4**) of the delivery tube **3**, for example they may be interconnected on a printed circuit board, overmoulded with plastic for sealing and mounted in the gases stream through the delivery conduit as shown in FIG. **4**. Furthermore, the circuit may be formed by interconnected parts in a housing, for example, a plastic housing, that protrudes from the plastic wall of the delivery tube into the gases flow through the conduit, in order to measure that gases properties. All other parts of the circuit **20** including the reference resistor **24** and the switching circuitry **29** would be included in the control circuitry of the humidifier **8**.

The thermistor's value can be chosen to have different resistance curves with known properties at ambient temperature. The choice of a particular thermistor value for use with the circuit allows identification by the control system of the present invention and matching of that thermistor value with a specific conduit or tubing **3**. Such that different thermistor values can be matched with a particular and appropriate conduit types and upon connection of the conduit to a humidifier or blower device, the control system can identify that thermistor and apply the appropriate control strategy to the heating of the conduit.

AC or DC Heating Voltage

The circuit shown in FIG. **2** is intended to be used when a DC heating voltage is used in conjunction with the heater wire, delivery conduit and system as shown in FIG. **1**. An alternative embodiment of a circuit **40** that would provide measurement of the gases properties, such as temperature and is suitable for AC and DC voltages, is shown in FIG. **3**. A number of voltage signals **51**, **52**, **53**, which are at different frequencies, are added together at an adder **50**. These signals include at least one heating signal **51** and at least one measuring signal **53**. The combination of these signals passes down the heater wire **44**, creating currents (heating and measuring) in the heater wire **44**. A number of parallel paths are established **41**, **43**, **45** each containing a filter (for example, as shown in FIG. **3**, one low pass filter **41** and three band pass filters **43**, **45**, **48**) that each pass a different frequency range. These parallel paths (that is, filters, thermistors and/or sensors) are preferably located at the end **30** of the delivery tube **3**, in a similar manner as described in relation to FIG. **2**. The parallel paths allow the heating current to be passed through a different path to the measurement currents. It also allows multiple measurement signals to be passed through the heater wire so that different properties of the gases (e.g. temperature, pressure, humidity, composition) may be measured.

The heating and measurement currents return through the heater wire **46** and can be filtered through a number of measurement filters **47**, **49**, **57** in parallel that pass frequency bands that correspond to the filters, **41**, **43**, **45** located at the end **30** of the tube **3**. The heating current takes a different path than the measurement currents. The measurement currents each take a different path depending on their frequency and this allows each measurement current to be measured by passing it through a reference resistor **48**, **54** or similar. Again a look up table or equation may be used to convert the voltage across the reference resistor **48**, **54** to, for example, a temperature. In the preferred embodiment of the present invention the measurement filters **47**, **49**, **57** would be included in the humidifier **8** control circuitry.

In a further embodiment one or more of the sensing elements **55**, **56** at the end **30** of the delivery tube **3** could be replaced by a fixed impedance to allow identification of the tube so that different control algorithms can be used for different conduits or tubes.

FIG. **4** shows a cutaway view of a conduit **3** with a printed circuit board **60** housing the parts to one of the circuits of the present invention described above with reference to FIG. **2** or **3**. The circuit board **60** is connected to the heating wires **21**, **28** and as such is positioned within the conduit **3**. In this manner, the thermistor **23** included on the board **60** is exposed to the gases flowing through the conduit **3** and can provide measurements of the properties of the gases.

The circuits and method of the present invention can be applied to a number of applications of these technologies for humidification and breathing circuit products. For example, the measurement of the temperature or humidity at the end of the delivery tube (or in a patient interface, for example, nasal cannula or mask) can be used to better control the humidifier, such that a more accurate temperature of gases can be supplied to the patient, providing optimal patient comfort and therapy. Additionally, other gases properties may be measured, such as the gases pressure or gas composition near the patient.

The apparatus of the present invention eliminates the need for external wires for sensing gases properties, as is required by the prior art. Furthermore the apparatus of the present invention only uses two pins or contacts (as opposed to four pins as used in current heated tube implementations). This means the system of the present invention is likely to be more reliable as the contacts/pins are likely to be less prone to breakage. The utilisation of the heater wire for measuring gases properties may also reduce the cost of the breathing tube **3** and associated parts, especially if the breathing tube is to be disposable.

What is claimed is:

1. A conduit for supplying gases, the conduit comprising:
- a proximal end configured to connect to a source of breathing gases;
- a distal end configured to connect to a patient interface;
- a wall defining a lumen for delivering a flow of gases to a patient;
- a wire provided within or around the conduit and extending at least a portion of a length of the conduit, the length of the conduit extending from a proximal portion of the conduit to a distal portion of the conduit; and
- a gases property sensor configured to measure at least one property of the flow of gases and positioned at the distal portion of the conduit, the gases property sensor connected to the wire, and the gases property sensor disposed within a housing and within the flow of gases such that the gases property sensor is able to measure the at least one property of the flow of gases.

2. The conduit of claim **1**, wherein the gases property sensor comprises at least one of a thermistor or a capacitive sensor.

3. The conduit of claim **1**, wherein the gases property sensor is configured to measure at least one of temperature, pressure, gas composition, or humidity of the flow of gases.

4. The conduit of claim **1**, wherein the at least a portion of the length of the conduit is substantially the length of the conduit.

5. An apparatus configured to supply a stream of gases to a patient, the apparatus comprising:
- a gases supply;
- a conduit configured to connect to the gases supply and to deliver the stream of the gases to the patient;
- a wire located throughout a length of the conduit;
- an electrical circuit connected to the wire, the electrical circuit configured to provide a signal to a controller through the wire indicative of at least one property of the stream of gases, the controller configured to determine the at least one property of the stream of gases, wherein at least a portion of the electrical circuit is configured to be positioned within the stream of gases; and
- an overmolding enclosing at least part of the electrical circuit, the overmolding extending into a region conveying the stream of gases through the conduit.

6. The apparatus of claim **5**, wherein the overmolding comprises a housing protruding from a wall of the conduit into the stream of gases.

7. The apparatus of claim **6**, wherein the housing protrudes beyond the wall of the conduit.

8. The apparatus of claim **5**, wherein the electrical circuit is at least partially molded into a wall of the conduit.

9. The apparatus of claim **5**, wherein the electrical circuit comprises at least one of a thermistor, a resistor, or a capacitive sensor.

10. The apparatus of claim **9**, wherein the at least one of the thermistor, the resistor, or the capacitive sensor is positioned in the conduit at or near a middle of a lumen formed by a wall of the conduit, and wherein the stream of gases is delivered through the lumen.

11. The apparatus of claim **5**, wherein the electrical circuit is positioned on a circuit board, and wherein the overmolding encloses at least part of the circuit board.

12. The apparatus of claim **5**, wherein the electrical circuit is mounted on a circuit board that at least partially extends into the stream of gases supplied to the patient through the conduit.

13. The apparatus of claim **5**, wherein the electrical circuit is configured to measure at least one of temperature, pressure, gas composition, or humidity of the stream of gases.

14. The apparatus of claim **5**, wherein the conduit is configured to connect to the gases supply at a first end of the conduit and to connect to a patient interface at a second end of the conduit, the patient interface configured to deliver the gases stream to the patient, and wherein the length of the conduit is substantially from the first end to the second end.

15. The apparatus of claim **14**, wherein the overmolding is disposed at or near the second end of the conduit.

16. The conduit of claim **1**, wherein the gases property sensor is on a circuit board.

17. The conduit of claim **16**, wherein at least a portion of the circuit board is disposed within a plastic molding at least partially forming the housing.

18. The conduit of claim **17**, wherein the circuit board is at least partially molded within the wall of the conduit.

19. The conduit of claim **1**, wherein the housing protrudes beyond the wall of the conduit into the lumen.

20. The conduit of claim **1**, wherein the gas property sensor is positioned at or near a radial center of the lumen.

21. The conduit of claim **1**, further comprising a diode connected to the wire and in parallel electrical communication with the gases property sensor, wherein when an electrical current is applied to the wire in a first polarity, the electrical current flows through the diode such that the wire provides heat to the conduit, and wherein when the electrical current is applied to the wire in a second polarity opposite from the first polarity, the electrical current does not flow through the diode and flows through the gases property sensor.

22. The conduit of claim **21**, wherein the diode is positioned at the distal portion of the conduit.

23. The conduit of claim **1**, further comprising:

a first filter connected to the wire and in series electrical communication with the gases property sensor, the first filter configured to pass through an electrical signal of a first frequency range driven through the wire;

an other gases property sensor configured to measure at least one other property of the flow of gases and positioned at the distal portion of the conduit, the other gases property sensor connected to the wire in parallel electrical communication with the gases property sensor, and the other gases property sensor disposed within the housing and within the flow of gases such that the other gases property sensor is able to measure the at least one other property of the flow of gases; and

a second filter connected to the wire and in series electrical communication with the other gases property sensor, the second filter configured to pass through an electrical signal of a second frequency range driven through the wire,

wherein the electrical signal of first frequency range is associated with measuring the at least one property of the flow of gases, and

wherein the electrical signal of the second frequency range is associated with measuring the at least one other property of the flow of gasses.

24. The conduit of claim **1**, further comprising:

a third filter connected to the wire and in parallel electrical communication with the first and second filters, the third filter configured to pass through an electrical signal of a third frequency range driven through the wire,

wherein the electrical signal of the third frequency range is associated with providing heat to the conduit via the wire.

25. The conduit of claim **2**, wherein the gases property sensor comprises a resistor and the capacitive sensor.

26. The conduit of claim **17**, wherein the plastic molding protrudes from the wall of the conduit into the flow of gases.

27. The apparatus of claim **5**, wherein the gases supply includes the controller configured to determine the at least one property of the stream of gases.

28. The apparatus of claim **5**, wherein the electrical circuit further comprises a sensor and a diode, the sensor configured to provide the signal to the controller through the wire indicative of the at least one property of the stream of gases, the diode in parallel electrical communication with the sensor, wherein when an electrical current is applied to the wire in a first polarity, the electrical current flows through the diode such that the wire provides heat to the conduit, and wherein when the electrical current is applied to the wire in a second polarity opposite from the first polarity, the electrical current does not flow through diode and flows through the sensor.

29. The apparatus of claim **28**, wherein the diode is positioned at a distal portion of the conduit, the distal portion configured to connect to a patient interface.

30. The apparatus of claim **28**, wherein the controller comprises a reference resistor in electrical communication with the sensor via the wire, wherein when the electrical current is applied to the wire in the second polarity and the electrical current flows through the sensor, the controller is configured to determine the at least one property of the flow of gases via the reference resistor.

31. The apparatus of claim **5**, wherein the electrical circuit further comprises:

a first sensor configured to provide a first signal to the controller through the wire indicative of a first property of the at least one property of the stream of gases;

a first filter in series electrical communication with the first sensor, the first filter configured to pass through to the first sensor a first electrical frequency range driven through the wire, the first electrical frequency range associated with the first signal;

a second sensor configured to provide a second signal to the controller through the wire indicative of a second property of the at least one property of the stream of gases, the second sensor in parallel electrical communication with the first sensor;

a second filter in series electrical communication with the second sensor, the second filter configured to pass through to the second sensor a second electrical frequency range driven through the wire, the second electrical frequency range associated with the second signal; and

a third filter in parallel electrical communication with the first and second filters, the third filter configured to pass through a third frequency range driven through the wire, the third frequency is associated with providing heat to the conduit via the wire.

32. The apparatus of claim **31**, wherein the controller comprises:

a first reference resistor in electrical communication with the wire, the first reference resistor associated with the controller determining the first property of the at least one property of the stream of gases;

a fourth filter connected to the wire and configured to pass through to the first reference resistor the first electrical frequency range associated with the first signal;

a second reference resistor in electrical communication with the wire, the second reference resistor associated with the controller determining the second property of the at least one property of the stream of gases; and

a fifth filter connected to the wire and configured to pass through to the second reference resistor the second electrical frequency range associated with the second signal.

33. The apparatus of claim **9**, wherein the at least one of the thermistor, the resistor, or the capacitive sensor is positioned in the conduit at or near a radial center of a lumen formed by a wall of the conduit, and wherein the stream of gases is delivered through the lumen.

* * * * *

EXHIBIT 6

US008550072B2

(12) **United States Patent**
Thudor et al.

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(45) **Date of Patent: *Oct. 8, 2013**

(54) **APPARATUS FOR DELIVERING HUMIDIFIED GASES**

(75) Inventors: **Mohammad Thudor**, Auckland (NZ); **Ian Douglas Makinson**, Auckland (NZ); **Philip James Biggs**, Auckland (NZ); **Philip John Dickinson**, Auckland (NZ)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

(60) Division of application No. 11/428,704, filed on Jul. 5, 2006, now Pat. No. 8,091,547, which is a division of application No. 10/246,328, filed on Sep. 18, 2002, now Pat. No. 7,111,624, which is a continuation-in-part of application No. 09/808,567, filed on Mar. 14, 2001, now Pat. No. 6,918,389.

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A61M 16/00 (2006.01)

(52) **U.S. Cl.**
USPC **128/203.17**; 128/203.16; 128/203.12

(58) **Field of Classification Search**
USPC 128/203.16, 204.17, 203.17, 203.12, 128/203.26, 203.27
See application file for complete search history.

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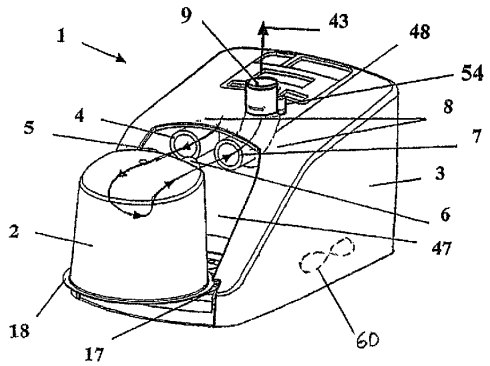
(57) **ABSTRACT**

An apparatus for delivering humidified gases has a connection manifold adapted to connect with inlet and outlet ports of a slide on water chamber in a single slide on motion. Connection of the gases inlet and gases outlet ports as well as any additional electrical and/or pneumatic connections are all made in the same slide on motion. The water chamber may include inwardly extending elongate extension tubes with one of the extension tubes having an air bleed aperture to aid filling of the chamber.

13 Claims, 7 Drawing Sheets



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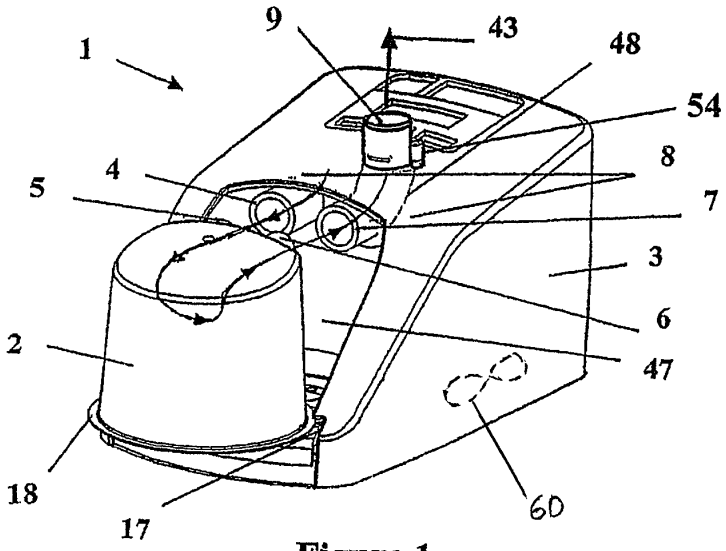

Figure 1

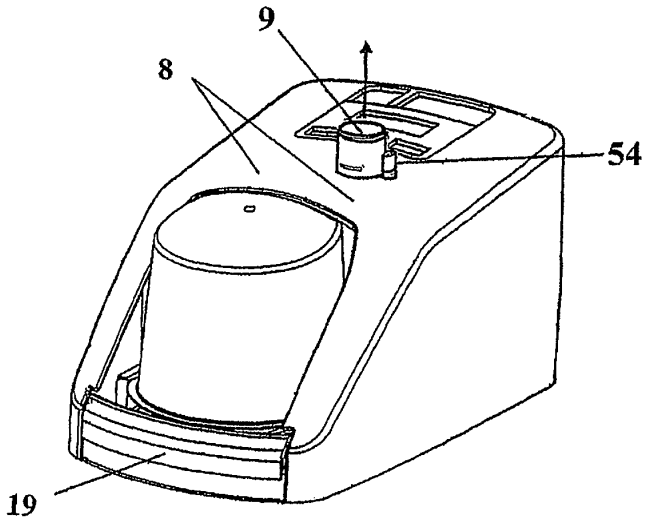

Figure 2

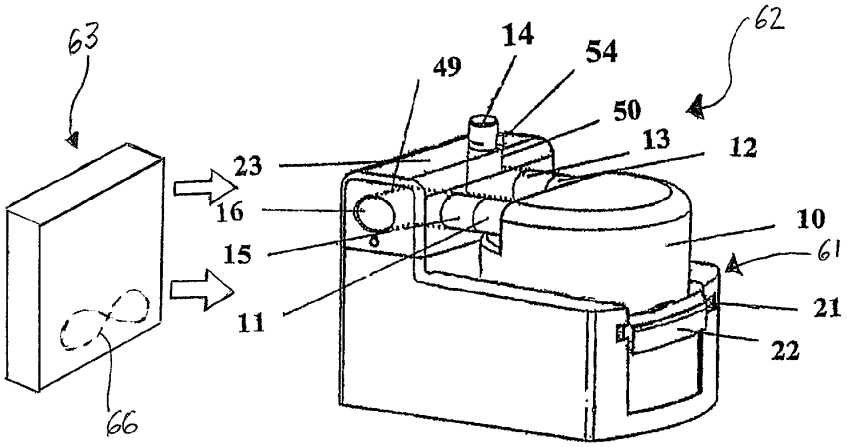

Figure 3

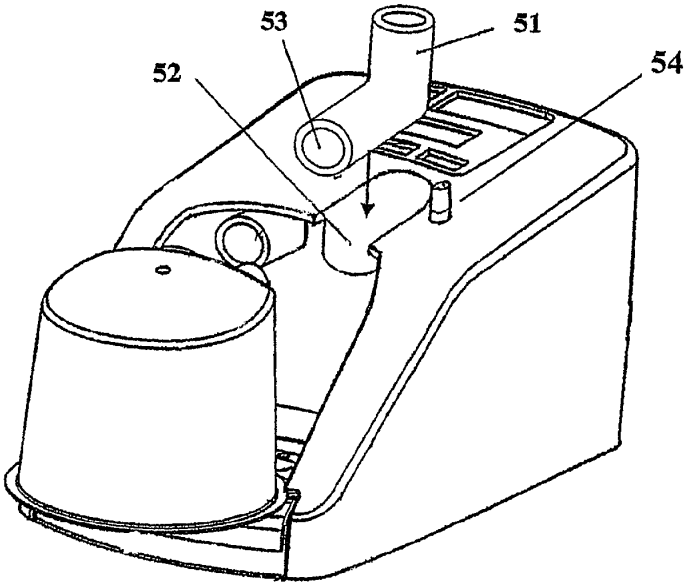

Figure 4

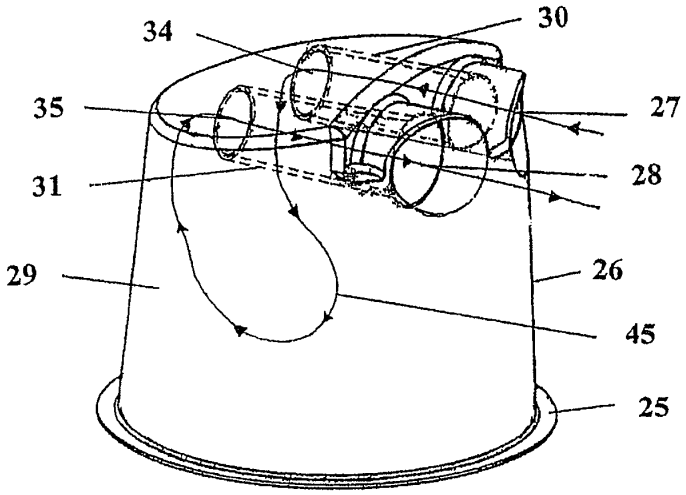

Figure 5

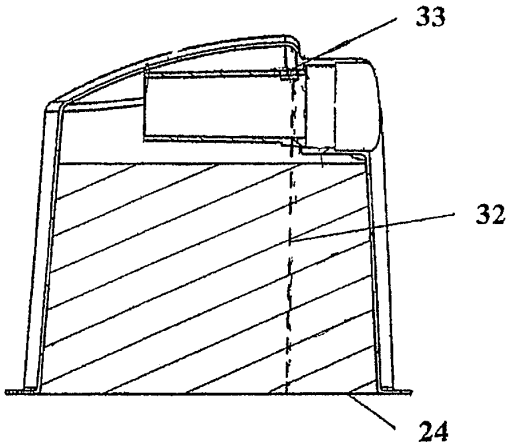

Figure 6

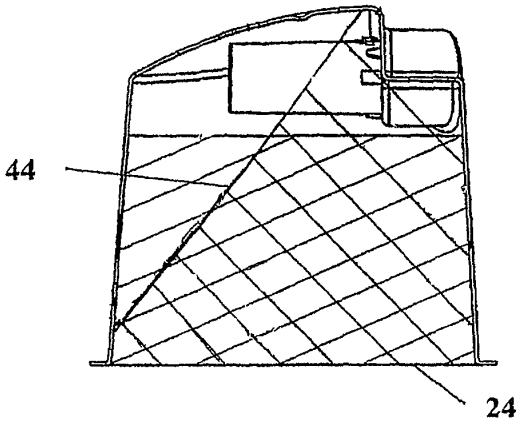

Figure 7

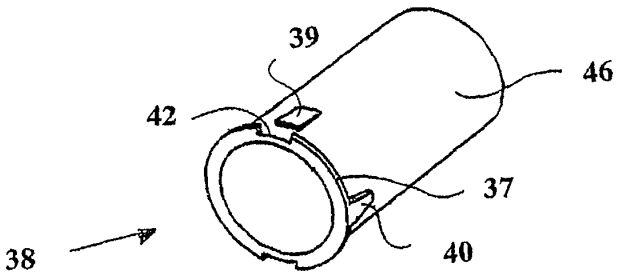

Figure 8

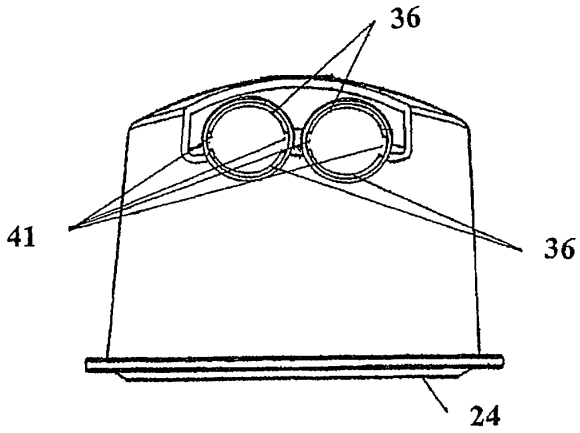

Figure 9

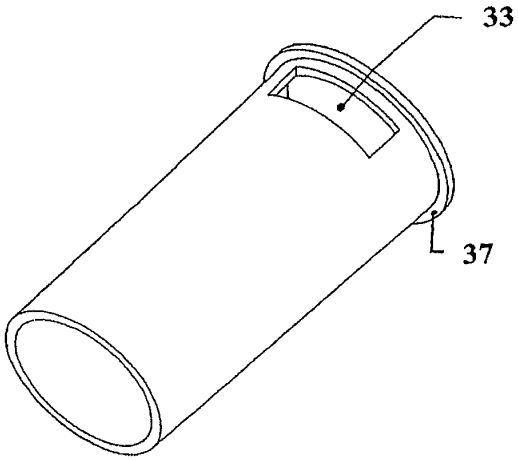

Figure 10

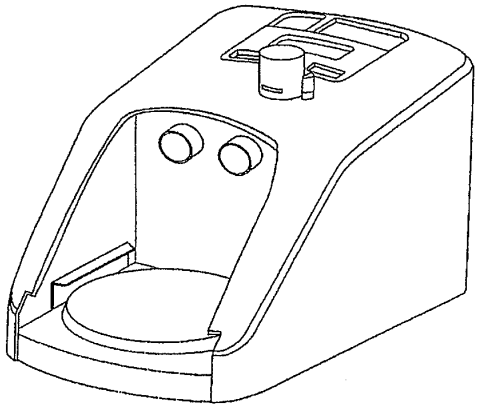

Figure 11

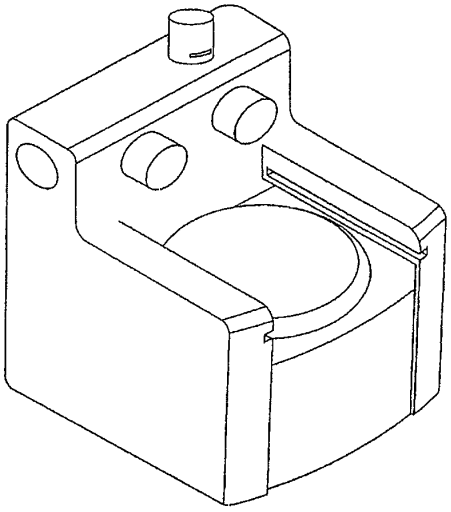

Figure 12

APPARATUS FOR DELIVERING HUMIDIFIED GASES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a division of U.S. patent application Ser. No. 11/428,704, filed Jul. 5, 2006, which is a division of U.S. patent application Ser. No. 10/246,328, filed Sep. 18, 2002, which issued as U.S. Pat. No. 7,111,624, Sep. 26, 2006, which is a continuation-in-part of U.S. patent application Ser. No. 09/808,567, filed Mar. 14, 2001, which issued as U.S. Pat. No. 6,918,389, Jul. 19, 2005, each of which is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to apparatus for delivering humidified gases. In particular it relates to a humidifier arrangement for use in standalone humidifiers used for example in providing respiratory assistance to patients receiving mechanical ventilation or respiratory support and/or integrated humidifiers included for example in consumer CPAP delivery devices.

2. Description of the Related Art

Humidification systems are known which include a heater base and a disposable humidifier chamber which is fitted onto the heater base and within which a supply of water can be heated by the heater base. Air enters the humidifier chamber through an inlet air port in the roof of the chamber where it is humidified by the evaporation of water from the water supply before leaving the chamber through an exit port in the roof of the humidifier chamber.

Humidifier chambers of this type are also now used in compact and portable ventilation machines, for example machines intended for the home treatment of obstructive sleep apnea (CPAP machines). Where the humidifier base is adapted for use with slide-on humidifier chambers, and the connection of the chamber to the machine is accomplished with a single sliding movement, the inlet air port is provided horizontally through the side of the chamber. Air enters the humidifier chamber through the inlet air port and the humidified air leaves the humidifier chamber into a breathing conduit through an exit port in the top of the humidifier chamber.

A disadvantage of these configurations is the need to disconnect the patient breathing conduit from the top of the humidifying chamber in a separate operation before removal of the chamber for the purpose of refilling. A further disadvantage of these configurations is that separate electrical wiring connections are required to make use of a heated respiratory conduit.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an apparatus for delivering humidified gases which at least goes some way towards overcoming the above disadvantages or which will at least provide the public with a useful choice.

In a first aspect the invention consists in an apparatus for use in humidified gases delivery treatment comprising a first housing including a heater base, a pressurized gases outlet adapted to make separable fluid connection with an inlet of a water chamber, a humidified gases return adapted to make separable fluid connection with an outlet of said chamber, and being adjacent to, and aligned with said pressurized gases outlet, such that both said separable connections are made by a single motion, and said single motion also urges a base of said chamber in contact with said heater base, a second housing including a blower for generating a supply of pressurized gases, said second housing adapted to engage with said first housing and make fluid connection between said blower and said pressurized gases outlet, said apparatus further comprising a patient outlet in fluid connection with said humidified gases return for delivering gases to a patient via a breathing tube.

According to a further aspect said pressurized gases outlet and said inlet of a water chamber have between them first complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of the male and female connectors, and said humidified gases return and said outlet of said water chamber have between them second complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of the male and female connectors, said preferred insertion direction of said first connectors being parallel with said preferred insertion direction of said second connectors, and being parallel with the direction of at least a terminal part of said single motion.

According to a further aspect said patient outlet includes a connector for receiving a breathing tube and at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electrical or pneumatic connectors.

According to a further aspect said gases return and said patient outlet are separable from said apparatus.

According to a further aspect said apparatus further comprises an elbow tube having a first inlet end and a second outlet end; and said first inlet end of said elbow tube comprises said gases return, and said second outlet end of said elbow tube comprises said patient outlet.

In a further aspect the invention consists in an apparatus for use in humidified gases delivery treatment comprising a blower for generating a supply of pressurized gases, a pressurized gases outlet in fluid connection with said supply of pressurized gases and adapted to make separable fluid connection with an inlet of a water chamber in order to provide gases flow to said chamber, a humidified gases return, adapted to make separable fluid connection with an outlet said chamber in order to receive humidified gases from said chamber, and being adjacent to, and aligned with said pressurized gases outlet, such that both said separable connections are made by a single motion, and a patient outlet, in fluid connection with said humidified gases return in order to receive humidified gases from said humidified gases return and provide humidified gases to said patient outlet, said patient outlet being in fluid connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient.

According to a further aspect said apparatus includes a chamber heater said single motion also urges a base of said chamber in contact with said heater base.

According to a further aspect said pressurized gases outlet and said inlet of said water chamber have between them first complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of the male and female connectors, and said humidified gases return and said outlet of said water chamber have between them second complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of the male and female connectors, and said preferred insertion direction of said first connectors being parallel with said preferred inser-

tion direction of said second connectors, and being parallel with the direction of at least a terminal part of said single motion.

According to a further aspect said inlet of said chamber and said outlet of said chamber are each a female port, and said pressurized gases outlet and said humidified gases return are each a resilient tubular projection fitting within respective female ports with said chamber engaged.

According to a further aspect said protruding tubes of said pressurized gases outlet and humidified gases return have substantially parallel axis of extension, and said heater includes a substantially planar heating plate, and said axis of extension of said tubes are substantially parallel with the plane of said heating plate.

According to a further aspect said patient outlet includes a connector for receiving a breathing hose and at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electrical or pneumatic connectors.

According to a further aspect said gases return and said patient outlet are separable from said apparatus.

According to a further aspect said apparatus further comprises an elbow tube having a first inlet end and a second outlet end; and said first inlet end of said elbow tube comprises said gases return, and said second outlet end of said elbow tube comprises said patient outlet.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

Two preferred embodiments of the present invention will, now be described with reference to the drawings.

FIG. **1** is a perspective view of a water chamber and CPAP machine according to the first preferred embodiment of the present invention showing the water chamber **2** separated from the CPAP machine **1** and an arrow **43** indicating the path of air flow through the connection manifold of the CPAP machine and chamber.

FIG. **2** is a perspective view of a water chamber and CPAP machine according to the first preferred embodiment of the present invention showing the water chamber **2** engaged with the CPAP machine **1** as in use and an arrow indicating the exit path of air flow through the conduit connection manifold **9**.

FIG. **3** is a perspective view of a water chamber and humidifier base according to the second preferred embodiment of the present invention showing the water chamber **10** engaged in the connection manifold **23** of the heater base as in use.

FIG. **4** is a perspective view of a CPAP machine and water chamber according to an alternative embodiment of the present invention.

FIG. **5** is a perspective view of a water chamber of the present invention showing hidden detail of the inlet and outlet extension tubes.

FIG. **6** is a sectioned side view of the water tube of FIG. **5** section through a midline of the outlet extension tube with the intended water level shown hatched.

FIG. **7** is a sectioned side view of the water chamber of FIG. **5** sectioned through a mid-line of the chamber with the water level of the chamber when tilted shown hatched.

FIG. **8** is a perspective view of an inlet/outlet extension tube according a preferred embodiment of the present invention showing snap-fit protrusions and locating/locking means.

FIG. **9** is a front view of a water chamber of the present invention showing the flanges and notches which co-operate with the extension tubes detailed in FIG. **8**.

FIG. **10** is a perspective view of an outlet extension tube according to a preferred embodiment of the present invention showing the air bleed slot.

FIG. **11** is a perspective view of the CPAP machine of FIG. **2**.

FIG. **12** is a perspective view of the humidifier base of FIG. **3**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Two preferred embodiments of the present invention will now be described in detail.

Referring to FIGS. **1** and **2**, a first preferred embodiment of a CPAP machine and corresponding water chamber is shown. A water chamber having a gases inlet port **5** and gases outlet port **6** is shown with a portable CPAP machine, wherein the CPAP machine is adapted to receive slide-on chambers and which makes connection to the gases inlet/outlet ports of the water chamber through a connection manifold. Connection of the gases inlet and gases outlet ports are made to the connection manifold **8** of the CPAP machine in the same slide-on motion. The connection manifold also provides an auxiliary outlet connection port **9** suitable for receiving a flexible respiratory conduit to deliver humidified air to a patient.

The CPAP machine includes a heater base in a chamber receiving bay **47** to heat the water chamber, and a securing means for securing the water chamber to the CPAP machine. The securing means is provided by a securing latch **19** and a slot **17** around the periphery and of the chamber receiving bay **47**. The slot co-operates with a flange **18** around the base of the water chamber to secure the chamber when in use. The securing latch **19** operates to prevent removal of the chamber once it has been engaged. The securing means and connection manifold are arranged with a parallel axis of operation such that connection of the chamber inlet and outlet ports **5** & **6**, to the connection manifold **8** is achieved as well as securing of the chamber into the CPAP machine in the same slide-on motion.

The latch **19**, having a locking position and a release position, is biased toward the locking position which prevents removal of the chamber from the CPAP machine. The front face of the latch is shaped such that during the single slide-on motion employed to fit the water chamber to the CPAP machine the flange **18** urges the securing latch **19** into the release position and allows the water chamber to be properly fitted. Once the water chamber is properly seated on the heater base and the inlet **5** and outlet **6** is properly engaged with the connection manifold **8**, the flange **18** and base of the chamber will no longer be in contact with the securing latch **19**. This allows the securing latch biasing means to urge the latch into the locking position and prevent the water chamber from being removed as shown in FIG. **2**.

Preferably the connection manifold **8** includes a passage which receives airflow from the blower **60** and directs it into the water chamber **2**, as well as a passage which directs airflow received via the water chamber outlet port **6**, to the CPAP patient outlet port **9**. The connection passage connecting the manifold inlet port **7**, to the manifold patient outlet port **9** is shown in hidden detail **48** in FIG. **1**. Preferably the

connection manifold **8** of the present invention is removable to aid cleaning and/or sterilization of the passages. In one preferred embodiment the above connection passages are internal to the connection manifold **8** as illustrated in FIGS. **1** and **2**.

In use air from the CPAP machine blower **60** exits through outlet port **4**, and enters the chamber **2** through inlet port **5**. Air entering the chamber is humidified by the evaporation of water from the water source in the bottom of the chamber before leaving the chamber through the patient outlet port **6**. Humidified air from the outlet port **6** is received into the connection manifold of the CPAP machine **8** via the inlet port **7**. The connection manifold **8** directs air to the outlet port **9** which is adapted to connect with a flexible conduit connector for delivery to a patient. An advantage obtained from the breathing conduit connection **9** being located on the body of the CPAP machine and not connected to the top of the water chamber directly, is that complete connection or disconnection of the water chamber from the CPAP system can be achieved with a single slide-on or slide-off motion. This feature makes removal of the water chamber for refilling considerably simpler.

A further advantage is obtained when additional electrical or pneumatic connections are required. The use of heated conduits requires electrical wiring connectors between the conduit and humidified air source while an additional pneumatic connection may be used for pressure feedback or measurement. In the present invention the connector which includes an additional electrical and/or pneumatic connection **54** for the conduit is integral to the connection manifold of the CPAP machine **8** and therefore allows the disposable water chamber to remain as simple as possible.

Referring to FIG. **3**, a second preferred embodiment of an in-line humidifier and corresponding water chamber is shown. A water chamber having a gases inlet port **11** and gases outlet port **12** is shown with an in line humidifier, wherein the humidifier is adapted to receive slide-on chambers and which makes connection to the gases inlet/outlet ports of the water chamber through a connection manifold **23**. Connection of the gases inlet and gases outlet port is made through the connection manifold **23** of the humidifier in the same slide-on motion. The connection manifold has an auxiliary inlet port **16** suitable for connection of a flexible conduit for delivery of airflow to the humidifier and an auxiliary patient outlet port **14** suitable for receiving flexible respiratory conduits to receive the humidified air flow.

Preferably the connection manifold **23** includes a passage **49** which receives airflow from the inlet conduit through inlet port **16** and directs it into the water chamber inlet port **11** through manifold outlet port **15**. Preferably the connection manifold **23** also includes a passage **50** which receives airflow from the water chamber outlet port **12**, via manifold inlet port **13** and directs it to the manifold patient outlet port **14**. The connection passages **49** and **50** are shown in hidden in FIG. **3**. Preferably the connection manifold **23** of the present invention is removable to aid cleaning and/or sterilization of the passages. Preferably the connection passages are internal to the connection manifold **23**.

The humidifier includes a heater base to heat the water chamber and a securing means for securing the water chamber to the humidifier. The securing means is provided by a securing latch **22** and a slot **21** around the periphery and of the chamber receiving bay. The slot co-operates with a flange around the base of the water chamber **10** to secure the chamber when in use, while the securing latch operates to prevent removal of the chamber once it has been engaged. The securing means and connection manifold are arranged such that connection of the chamber inlet and outlet ports **11** and **12**, to the connection manifold **23** is achieved at the same time as securing of the chamber into the humidifier in the same slide-on motion. The latch **22**, having a locking position and a release position, is biased toward the locking position which prevents removal of the chamber from the humidifier. The front face of the latch **22** is shaped such that during the single slide-on motion employed to fit the water chamber to the humidifier the flange urges the securing latch **22** into the release position and allows the water chamber **10** to be properly fitted. Once the water chamber is properly seated on the heater base and the inlet **11** and outlet **12** is properly engaged with the connection manifold **23**, the flange and base of the water chamber will no longer be in contact with the securing latch **22** This allows the securing latch biasing means to urge the latch into the locking position and prevent the water chamber from being removed.

In use the humidifier inlet port **16** receives air flow through a flexible conduit. Air leaves the connection manifold **23** through the outlet port **15** and enters the water chamber **10** through the chamber inlet port **11**, where it is humidified by the evaporation of water from the water supply. Humidified air leaves the water chamber via outlet port **12**, enters the humidifier connection manifold inlet port **13**, finally exiting through the patient outlet port **14** into a breathing conduit for delivery to a patient. An advantage obtained by having both the inlet **16** and outlet **14** which connect to conduits, integral to the body of the humidifier and not part of the water chamber directly, is that complete connection/disconnection of the water chamber **10** from the humidifier base can be achieved with a single slide-on/off motion. This feature makes removal of the water chamber for refilling considerably simpler.

In a similar manner to the first preferred embodiment of a CPAP machine, a further advantage obtained from the configuration of the second preferred embodiment, arises when an additional electrical or pneumatic connection is required. The inlet and/or outlet connectors including an electrical and/or pneumatic connection **54** for the conduit are integral to the connection manifold of the humidifier and therefore allow the disposable water chamber to remain as simple as possible.

A number of alternative variations of the first and second preferred embodiments are envisaged and will now be described. For example, a further embodiment of the present invention is envisaged to deliver humidified gases from the water chamber to a patient via a flexible breathing conduit. This alternative embodiment is shown in FIG. **4**. An elbow tube **51** having an inlet end and an outlet end is provided to receive humidified gases from the water chamber and direct humidified gases into a flexible breathing conduit for delivery to a patient. In this alternative preferred embodiment the CPAP machine housing is provided with a recess **52** for receiving and securing the elbow tube. For example the recess **52** may include a neck or constriction that is above the elbow **51** when elbow **51** is in place. The neck holds the elbow in place under normal usage, but the elbow can be forcibly removed when required. When secured in position, an inlet **53** of the elbow tube **51** is positioned to make a fluid connection to the outlet **6** of the water chamber in the same slide on motion. In this alternative embodiment the outlet elbow may be part of the termination of the breathing tube instead of an internal part of the connection manifold as previously described. An advantage of this alternative embodiment is that all the parts in contact with condensation are removable for cleaning or sterilization. This embodiment also retains the advantage of an engagable/disengagable water chamber in a single slide on/off motion. This embodiment may also include additional electrical or pneumatic connections **54** for

making a connection between the CPAP machine and a conduit connector, enabling this alternative to retain the advantages of the previously described embodiments. While FIG. **4** shows this alternative preferred embodiment of the present invention applied to a CPAP machine it is envisaged that this embodiment may also be applied in an analogous manner to an inline humidifier such as that described in the second embodiment of the present invention and pictured in FIG. **3**.

An alternative embodiment of the present invention is envisaged wherein a water chamber **10** and heater base **61** are partially or fully enclosed in a housing **62**. The housing **62** includes a connection manifold **23** consisting of at least one gases inlet **15** and at least one gases outlet **13** connection port being adjacent and aligned, which in use transport gases to and/or from the water chamber **10**. A second housing **63** is provided with complementary inlet and outlet connections for registration with the connection manifold **23**. The second housing **63** is adapted to engage with the first housing **62** making all the necessary gases and electrical connections in the same slide-on motion and preferably includes a securing means. The second housing **63** may include an integral air blower **66**, and a patient conduit outlet port in the case of a CPAP embodiment. Or in the case of an in-line humidifier embodiment, the second housing may include two conduit ports. The first conduit port in use receiving air from a source and the second conduit port delivering humidified air to a patient. The above described embodiment has the advantage that all necessary flexible conduit connections are made on the second housing. This enables the water chamber and/or enclosing housing to be removed/engaged in the same slide-off/on motion making refilling of the chamber simpler.

In the first and second preferred embodiments of the present invention, tubular protrusions are provided for making a connection between the humidifier apparatus and a water chamber in order to deliver gases to the chamber and receive humidified gases from the chamber. Preferably the tubular protrusions also include a resilient boot in order to provide an improved seal between the water chamber and the protrusions.

A further embodiment of the present invention is envisaged wherein the connections between the apparatus manifold and the water chamber are not provided side by side as described in the first and second embodiment of the present invention but rather are provided one within the other, for example the inlet and outlet may be coaxial. Such a configuration would enjoy the same advantages as the configurations described in more detail in the first and second embodiments of the present invention. It is also envisaged that such connections may also include similarly configured tubes for providing pressure measurements or pressure feedback.

While the above preferred embodiments describe male/female type connectors wherein the water chamber has two female connectors for mating with corresponding male connectors of the apparatus manifold, it is envisaged that many variations will present themselves to those skilled in the art without departing from the spirit of the present invention. For example the water chamber may be provided with two male connectors while the apparatus manifold is provided with corresponding female connectors, or the water chamber may be provided with one male and one female connector for connecting to the corresponding male and female connectors of the apparatus manifold. Further it is envisaged that connectors of an androgynous nature may be provided for making connection between the water chamber and the apparatus manifold wherein each connector may include both male type protruding portions and female type recess portions. Such connections may be particularly advantageous when the inlet and outlet is provided one within the other.

With reference to the first and second preferred embodiments of the present invention, some common features of a water chamber suitable for use with either preferred embodiment will now be described in more detail.

The chamber as shown in FIG. **5** is constructed from an open bottomed plastic container enclosed by a heat conductive base **24**, and includes a horizontally aligned gases inlet **27** and a parallel gases outlet **28**. It is envisaged that other configurations of the present invention are possible where the slide-on direction employed to fit the water chamber is not horizontal but at an angle from the horizontal or vertical. In such cases, the gases inlet **27** and outlet **28**, are preferably parallel and aligned with the direction of the intended slide-on motion to allow mating of the chamber inlet/outlet ports and the connection manifold.

The water chamber of the present invention preferably includes an inlet extension tube **30**, and an outlet extension tube **31**, extending inwardly into the chamber interior from the periphery of the chamber wall and preferably having a generally tapering body. The inlet extension tube **30** and the outlet extension tube **31** are preferably molded from the same clear thermoplastic material as the chamber shell **26**. The inclusion of inlet/outlet extension tubes has been found to significantly reduce noise produced by the airflow around the chamber. Preferably at least one extension tube has an air bleed aperture to aid filling of the chamber with the chamber tipped up. The air bleed is preferably located in the top surface of the extension tube and preferably toward the end of the extension tube which is connected to the chamber wall. Referring to FIG. **6**, preferably the air bleed aperture **33** is positioned such that when the tank is tipped up for filling, the air bleed valve height corresponds with the preferred fill height **32** for the water chamber. This feature aids in preventing overfilling of the water chamber.

Additionally, with reference to FIG. **7**, the extension tubes **30** and **31** may act as a weir against water flow back through the gases inlet and gases outlet, upon tilting of the chamber as shown by water level line **44**. If present, preferably the air bleed aperture **33** is present only on the outlet extension tube **31** and not present in the inlet extension tube **30**. This prevents water back-flow through the inlet port **27** occurring upon tilting of the chamber.

The present invention may further include a downwardly extending central baffle or rib located between the inlet and outlet extension tubes to ensure against gases short circuiting the chamber by flowing directly from the exit of the inlet extension tube **34**, to the entry of the outlet extension tube **35**. With the baffle the gases are forced to follow a more tortuous path ensuring adequate humidification during their journey through the chamber.

In use air is received into the chamber via inlet port **27** and travels down the inlet extension tube **30**. On exiting the inlet extension tube **30** air enters the chamber where it is humidified by the evaporation of water from the water supply. Humidified air flows from the chamber through the outlet extension tube **31** and exits through outlet port **28**. The above described flow path is illustrated in FIG. **5** by the arrow **45**.

Although the preceding description gives details of preferred embodiments having parallel and adjacent circular inlet/outlet ports, it is envisaged that other configurations are possible without departing from the spirit of the invention. For example the inlet/outlet ports of the chamber and connection manifold may have a non-circular cross section and not be symmetrical. Further it is possible that the position of the inlet port with respect to the outlet may take one of many

alternative configurations. For example the ports and there corresponding connections may also be co-axial or off-set, one inside the other.

Referring to FIGS. **8-10**, for ease of assembly the inlet and outlet extension tubes are preferably provided as a snap fit to their respective water chamber inlet or outlet, so that they can be pushed into the chamber through the inlet or outlet and, upon application of sufficient force, snap into a substantially watertight and secure condition.

To this end the inlet **27** and outlet **28** ports of the water chamber may be provided with an inwardly perpendicularly extending annular flange **36** at the inner end thereof and the inlet/outlet extension tubes **38** may include similar perpendicularly outwardly extending flanges **37** from one end of the generally tapering tubular body **46**. The flanges act together as sealing flanges in the fitted and assembled condition. To retain the extension tubes in the assembled condition, against both translational and rotational movement several securing mechanisms may be provided. In each case the securing mechanisms may be provided on either of the inlet/outlet (of the chamber) or the inlet/outlet extension tube. However it is preferred that they be on the extension tubes, as both components are intended for injection molding and injection molding of certain protrusions on the inner surface of the chamber inlet/outlet would be considerably more difficult than on the outer surface of the extension tubes. To secure the tubes against translational movement, and in a sealing condition between the sealing flanges, a plurality of retaining clip protrusions **39** may be provided spaced around the circumference of the tubular body of the extension tubes which cooperate with the inlet/outlet flange **36**. Particularly for ease of manufacture, and ensuring a simple two part injection mold, a notch **42** is allowed in the flange **37** of the extension tubes **38** adjacent the protrusion **39**.

To retain the extension tubes against rotational movement when snap fitted into location, one or more locating protrusions **40** may be provided circumferentially distributed on the outer surface of the tubular body adjacent and contiguous with the outwardly and perpendicularly extending flange **37**. The locating protrusions **40** are preferably generally tapered in both the circumferential and axial direction. Complementary notches **41** are provided in the inwardly extending flanges **36** of the chamber inlet and outlet. In fitting the extension tubes **38** the protrusions **40** are aligned with the notches **41**, and upon full insertion of the tubes, the protrusions **40** enter into a tight frictional fit with the notches **41** ensuring substantial if not complete sealing. It will be appreciated that the mechanism employed to ensure proper location and sealing of the extension tubes into the water chamber may take many forms. Many alternatives will suggest themselves to persons skilled in the art such as glued joints, various forms of plastic welding and various configurations of clipping means and protrusions. The above description is of one particular preferred embodiment and is not meant to be in any way limiting.

It will be readily appreciated that the construction of the water chamber as described is simple to manufacture and each of the plastic components is itself capable of simple injection molding. Consequently a water chamber according to the present invention is, while providing significant advantages, not significantly more expensive than existing chambers.

What is claimed is:

1. An apparatus for use in humidified gases delivery treatment comprising:

a first housing including:

a heater base,

a pressurised gases outlet adapted to make separable fluid connection with an inlet of a water chamber,

a humidified gases return adapted to make separable fluid connection with an outlet of said chamber, and being adjacent to, and aligned with said pressurised gases outlet, such that both said separable connections are made by a single motion, and

said single motion also urges a base of said chamber in contact with said heater base,

a second housing including a blower for generating a supply of pressurised gases, said second housing adapted to engage with said first housing and make fluid connection between said blower and said pressurised gases outlet,

said apparatus further comprising a patient outlet in fluid connection with said humidified gases return for delivering gases to a patient via a breathing tube.

2. An apparatus for use in humidified gases delivery treatment as claimed in claim **1**, wherein said pressurised gases outlet and said inlet of said water chamber have between them first complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of the male and female connectors, and

said humidified gases return and said outlet of said water chamber have between them second complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of the male and female connectors, said preferred insertion direction of said first connectors being parallel with said preferred insertion direction of said second connectors, and being parallel with the direction of at least a terminal part of said single motion.

3. An apparatus for use in humidified gases delivery treatment as claimed in claim **1**, wherein said patient outlet includes a connector for receiving a breathing tube and at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electrical or pneumatic connectors.

4. An apparatus for use in humidified gases delivery treatment as claimed in claim **1**, wherein said gases return and said patient outlet are separable from said apparatus.

5. An apparatus for use in humidified gases delivery treatment as claimed in claim **4**, wherein said apparatus further comprises an elbow tube having a first inlet end and a second outlet end; and

said first inlet end of said elbow tube comprises said gases return, and

said second outlet end of said elbow tube comprises said patient outlet.

6. An apparatus for use in humidified gases delivery treatment comprising:

a blower for generating a supply of pressurised gases,

a pressurised gases outlet in fluid connection with said supply of pressurised gases and adapted to make separable fluid connection with an inlet of a water chamber in order to provide gases flow to said chamber,

a humidified gases return, adapted to make separable fluid connection with an outlet said chamber in order to receive humidified gases from said chamber, and being adjacent to, and aligned with said pressurised gases outlet, such that both said separable connections are made by a single motion, and

a patient outlet, in fluid connection with said humidified gases return in order to receive humidified gases from said humidified gases return and provide humidified gases to said patient outlet, said patient outlet being in fluid connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient.

7. An apparatus for use in humidified gases delivery treatment as claimed in claim **6** wherein said apparatus includes a chamber heater and said single motion also urges a base of said chamber in contact with said heater.

8. An apparatus for use in humidified gases delivery treatment as claimed in claim **7**, wherein said pressurised gases outlet and said inlet of said water chamber have between them first complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of the male and female connectors, and

said humidified gases return and said outlet of said water chamber have between them second complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of the male and female connectors, and

said preferred insertion direction of said first connectors being parallel with said preferred insertion direction of said second connectors, and being parallel with the direction of at least a terminal part of said single motion.

9. An apparatus for use in humidified gases delivery treatment as claimed in claim **8**, wherein said inlet of said chamber and said outlet of said chamber are each a female port, and said pressurised gases outlet and said humidified gases return are each a resilient tubular projection fitting within respective female ports with said chamber engaged.

10. An apparatus for use in humidified gases delivery treatment as claimed in claim **9**, wherein said resilient tubular projections of said pressurised gases outlet and humidified gases return have substantially parallel axis of extension, and

said heater includes a substantially planar heating plate, and said axis of extension of said resilient tubular projections are substantially parallel with the plane of said heating plate.

11. An apparatus for use in humidified gases delivery treatment as claimed in claim **6**, wherein said patient outlet includes a connector for receiving a breathing hose and at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electrical or pneumatic connectors.

12. An apparatus for use in humidified gases delivery treatment as claimed in claim **6**, wherein said gases return and said patient outlet are separable from said apparatus.

13. An apparatus for use in humidified gases delivery treatment as claimed in claim **12**, wherein said apparatus further comprises an elbow tube having a first inlet end and a second outlet end; and

said first inlet end of said elbow tube comprises said gases return, and

said second outlet end of said elbow tube comprises said patient outlet.

* * * * *

EXHIBIT 7

US008091547B2

(12) **United States Patent**
Thudor et al.

(10) **Patent No.: US 8,091,547 B2**
(45) **Date of Patent: *Jan. 10, 2012**

(54) **APPARATUS FOR DELIVERING HUMIDIFIED GASES**

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(73) Assignee: **Fisher & Paykel Healthcare Limited**, Auckland (NZ)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1081 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/428,704**

(22) Filed: **Jul. 5, 2006**

(65) **Prior Publication Data**

US 2006/0237012 A1 Oct. 26, 2006

Related U.S. Application Data

(60) Division of application No. 10/246,328, filed on Sep. 18, 2002, now Pat. No. 7,111,624, which is a continuation-in-part of application No. 09/808,567, filed on Mar. 14, 2001, now Pat. No. 6,918,389.

(30) **Foreign Application Priority Data**

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(51) **Int. Cl.**
A61M 16/00 (2006.01)

(52) **U.S. Cl.** **128/203.17**; 128/203.16; 128/203.12

(58) **Field of Classification Search** 128/203.16, 128/204.17, 203.17, 203.12, 203.26, 203.27
See application file for complete search history.

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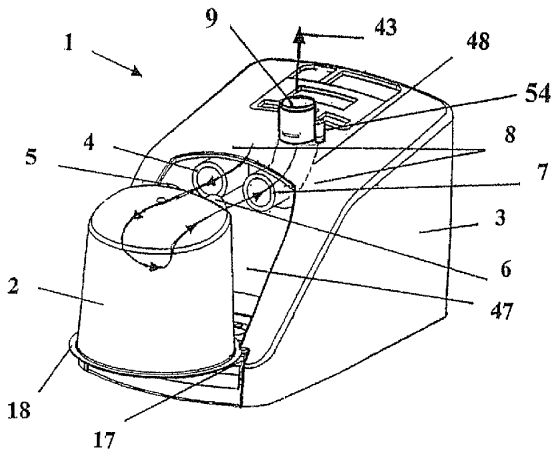
Primary Examiner — Justin Yu
Assistant Examiner — Rachel Young
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

An apparatus for delivering humidified gases has a connection manifold adapted to connect with inlet and outlet ports of a slide on water chamber in a single slide on motion. Connection of the gases inlet and gases outlet ports as well as any additional electrical and/or pneumatic connections are all made in the same slide on motion. The water chamber may include inwardly extending elongate extension tubes with one of the extension tubes having an air bleed aperture to aid filling of the chamber.

25 Claims, 7 Drawing Sheets



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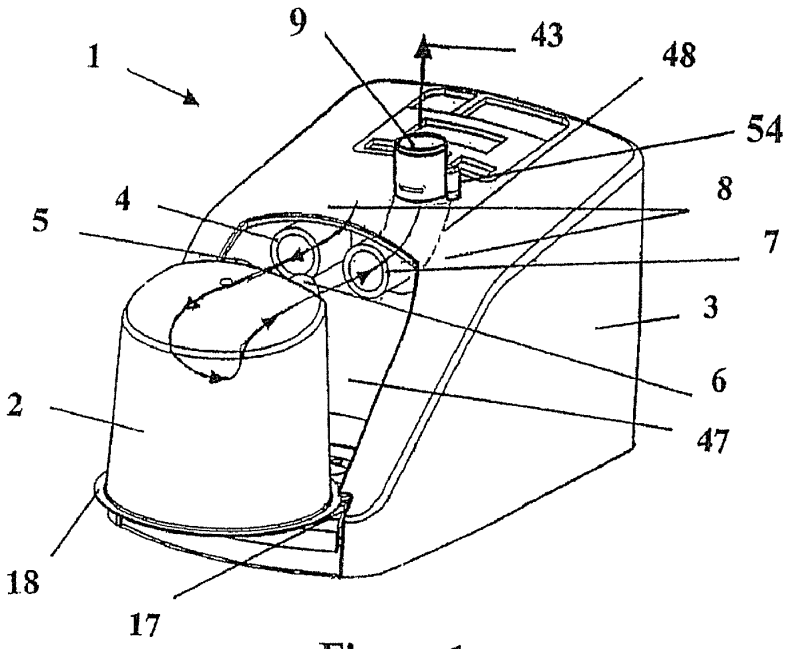


Figure 1

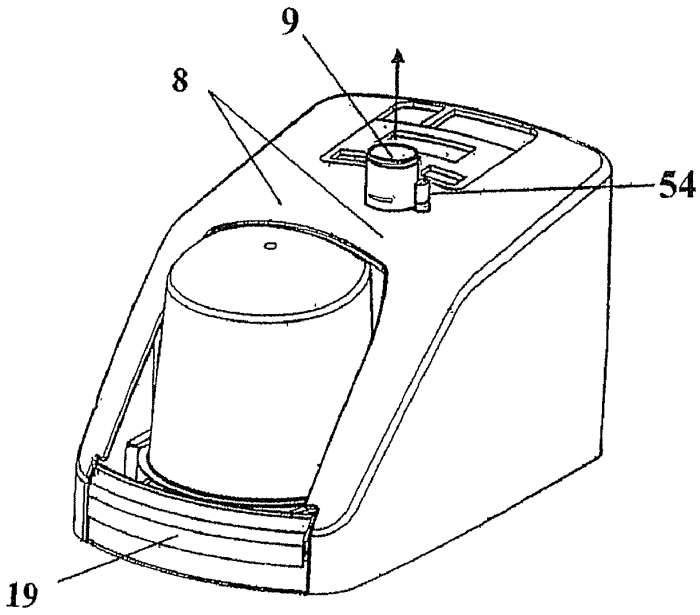


Figure 2

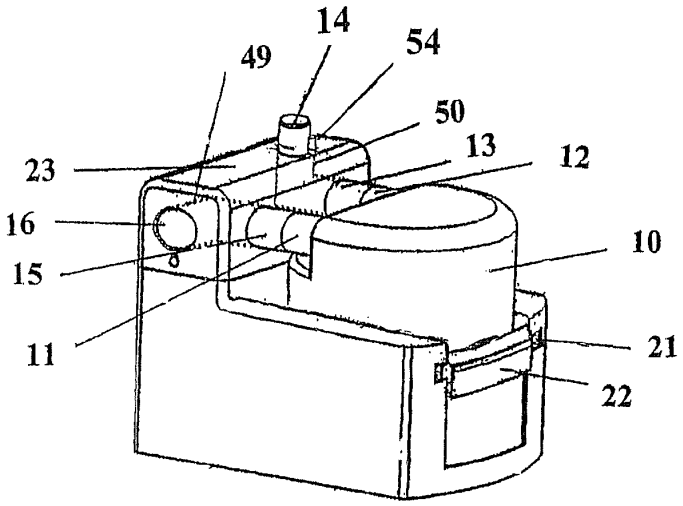


Figure 3

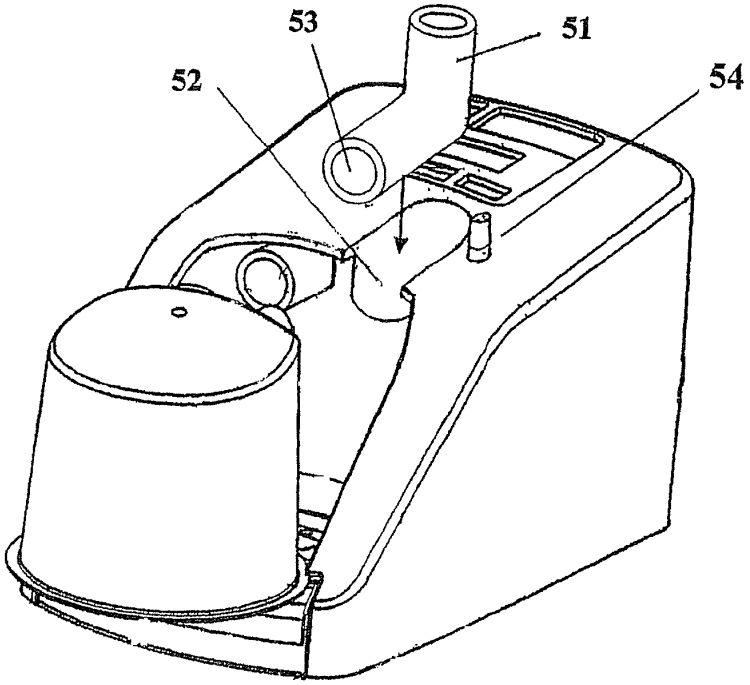


Figure 4

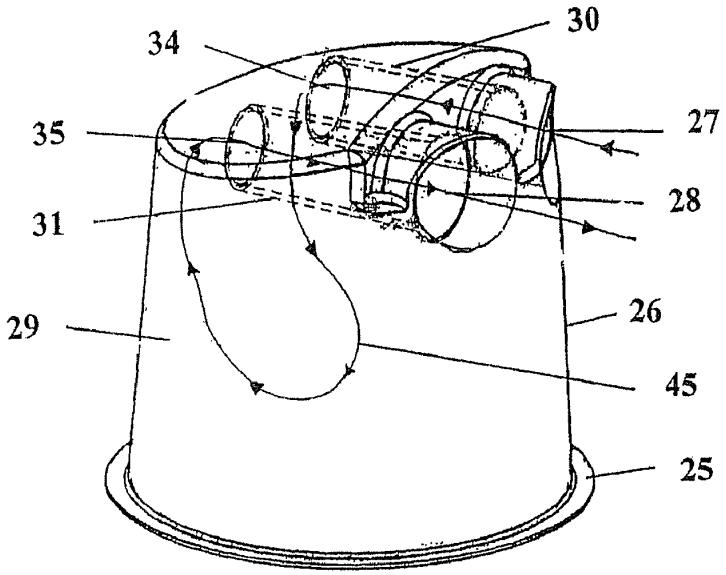


Figure 5

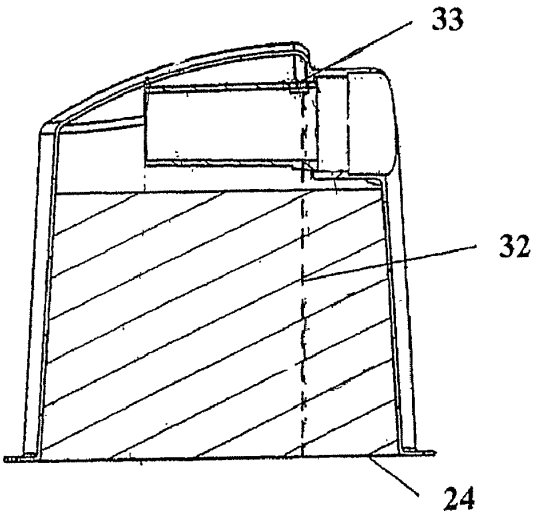


Figure 6

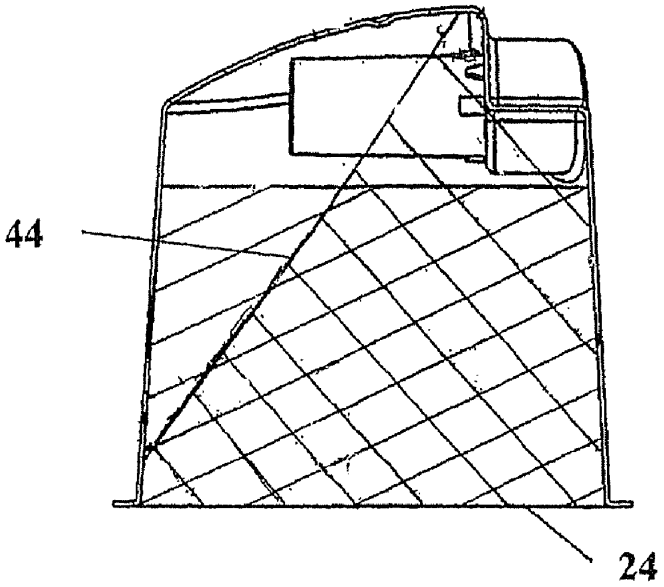


Figure 7

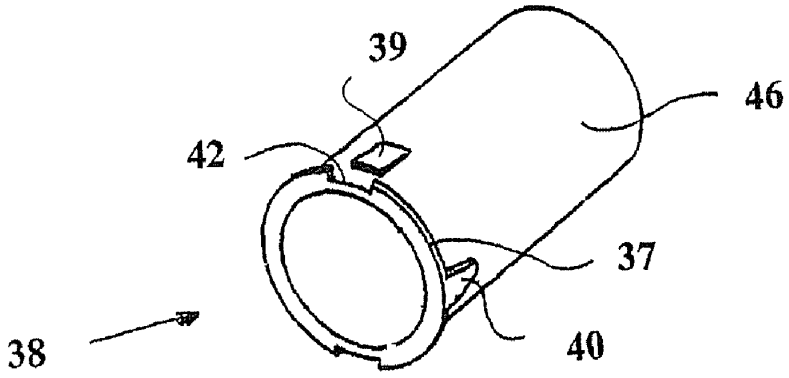


Figure 8

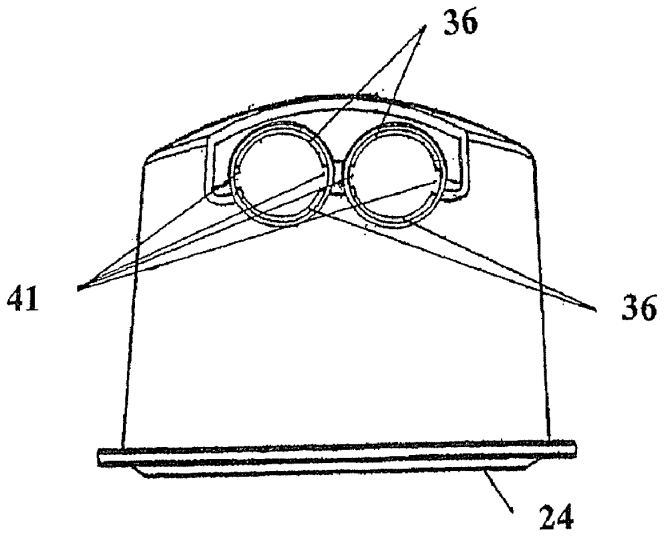


Figure 9

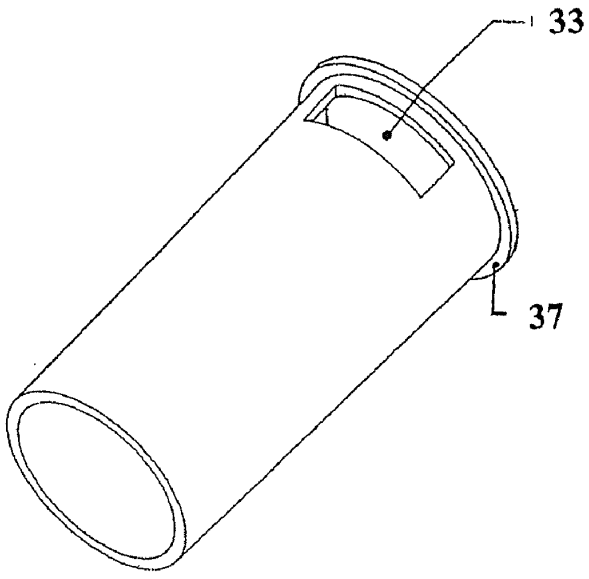


Figure 10

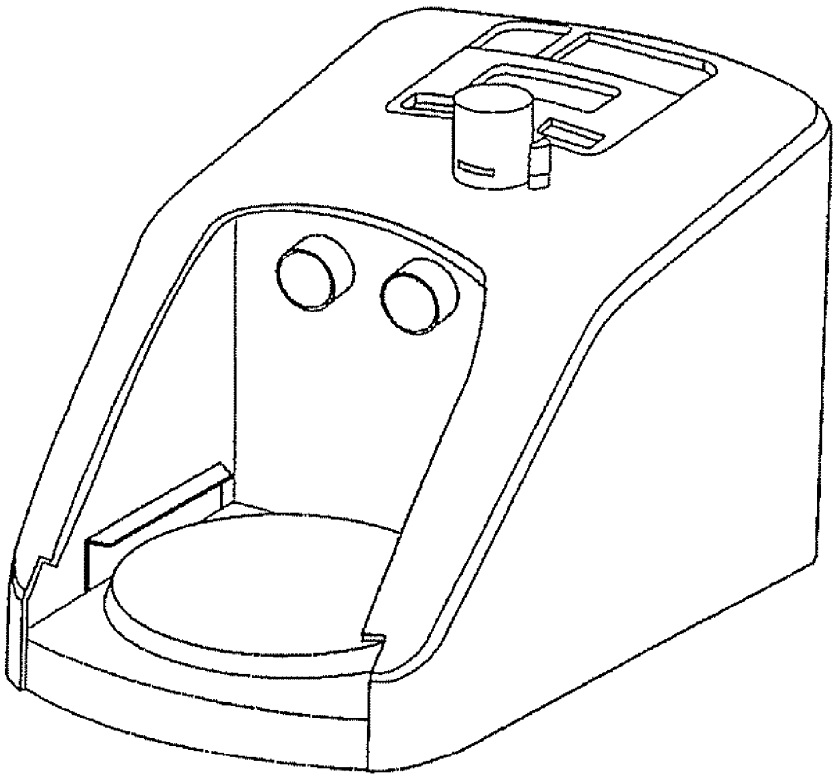


Figure 11

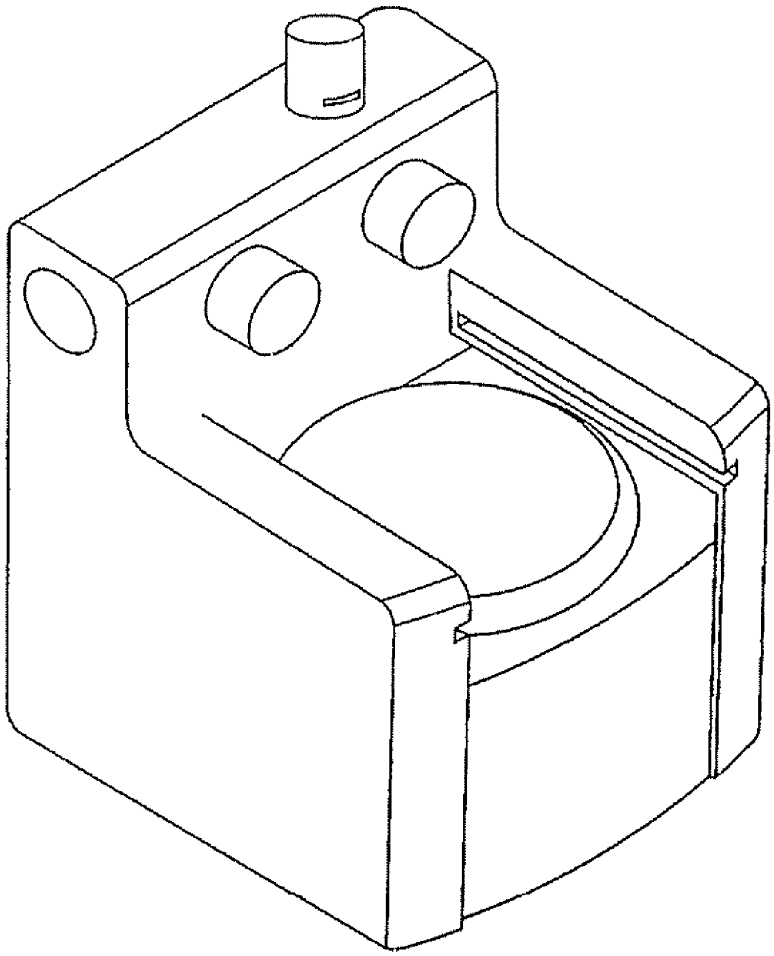


Figure 12

APPARATUS FOR DELIVERING HUMIDIFIED GASES

CROSS-REFERENCE AND INCORPORATION BY REFERENCE

This application is a Divisional of application Ser. No. 10/246,328, entitled "Apparatus for Delivering Humidified Gases" filed on Sep. 18, 2002, which, in turn, is a Continuation-In-Part of Ser. No. 09/808,567, entitled "Breathing Assistance Apparatus" filed on Mar. 14, 2001, now U.S. Pat. No. 6,918,389. Each of the aforementioned United States patents/applications are hereby incorporated by reference.

BACKGROUND TO THE INVENTION

i) Field of the Invention

The present invention relates to apparatus for delivering humidified gases. In particular it relates to a humidifier arrangement for use in stand alone humidifiers used for example in providing respiratory assistance to patients receiving mechanical ventilation or respiratory support and/or integrated humidifiers included for example in consumer CPAP delivery devices.

ii) Summary of the Prior Art

Humidification systems are known which include a heater base and a disposable humidifier chamber which is fitted onto the heater base and within which a supply of water can be heated by the heater base. Air enters the humidifier chamber through an inlet air port in the roof of the chamber where it is humidified by the evaporation of water from the water supply before leaving the chamber through an exit port in the roof of the humidifier chamber.

Humidifier chambers of this type are also now used in compact and portable ventilation machines, for example machines intended for the home treatment of obstructive sleep apnoea (CPAP machines). Where the humidifier base is adapted for use with slide-on humidifier chambers, and the connection of the chamber to the machine is accomplished with a single sliding movement, the inlet air port is provided horizontally through the side of the chamber. Air enters the humidifier chamber through the inlet air port and the humidified air leaves the humidifier chamber into a breathing conduit through an exit port in the top of the humidifier chamber.

A disadvantage of these configurations is the need to disconnect the patient breathing conduit from the top of the humidifying chamber in a separate operation before removal of the chamber for the purpose of refilling. A further disadvantage of these configurations is that separate electrical wiring connections are required to make use of a heated respiratory conduit.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an apparatus for delivering humidified gases which at least goes some way towards overcoming the above disadvantages or which will at least provide the public with a useful choice.

In a first aspect the invention consists in an apparatus for use in humidified gases delivery treatment comprising:

a housing,

a pressurised gases outlet in said housing adapted to make fluid connection with an inlet of a humidifier in order to provide gases flow to a said humidifier,

a humidified gases return in said housing, adapted to make fluid connection with an outlet of a said humidifier in order to receive humidified gases from said humidifier,

a patient outlet in said housing, in fluid connection with said humidified gases return in order to receive humidified gases from said humidified gases return and provide humidified gases to said patient outlet, said patient outlet being in fluid connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient.

In a further aspect the invention consists in an apparatus for use in humidified gases delivery treatment comprising:

a housing,

a pressurised gases supply within said housing,

a pressurised gases outlet in said housing in fluid connection with said pressurised gases supply and adapted to make fluid connection with an inlet of a humidifier in order to provide gases flow to a said humidifier,

a humidified gases return in said housing, adapted to make fluid connection with an outlet of a said humidifier in order to receive humidified gases from said humidifier,

a patient outlet in said housing, in fluid connection with said humidified gases return in order to receive humidified gases from said humidified gases return and provide humidified gases to said patient outlet, said patient outlet being in fluid connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient.

In a still further aspect the invention consists in an apparatus for use in humidified gases delivery treatment comprising:

a housing,

a gases line inlet in said housing to receive pressurised gases from a pressurised gases source, said gases line inlet adapted to make fluid connection with a breathing conduit,

a gases outlet in said housing in fluid connection with said gases line inlet, adapted to make a separable fluid connection with an inlet of said humidification chamber in order to provide gases flow into said humidification chamber,

a humidified gases return in said housing, adapted to make a separable fluid connection with an outlet of said humidification chamber in order to receive humidified gases from said humidification chamber,

a gases line outlet in said housing, in fluid connection with said humidified gases return, adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient,

a chamber heater in said housing for vaporising liquid water in said humidification chamber in order to provide water vapour to gases flow passing through said humidification chamber,

said housing adapted to accommodate a humidification chamber, said humidification chamber being removable and engageable with said housing via a single motion, and said single motion also

making a or breaking said separable fluid connection between said gases outlet and said humidification chamber inlet, and

said humidified gases return and said humidification chamber outlet,

In a still further aspect the invention consists in a humidifier chamber for use with a gases humidification apparatus comprising:

a container defining a water chamber having an aperture in the bottom, with a surrounding wall and top,

a heat conductive base enclosing said aperture in said bottom of said container,

a gases inlet to said container adapted to receive a substantially horizontal flow of gases into said container,

a gases outlet to said container adapted to receive a substantially horizontal flow of gases out of said container,

said gases inlet and said gases being parallel and aligned, such that said humidifier chamber may make operable engagement with a humidified gases delivery apparatus in a single motion,

wherein said single motion urging said heat conductive base adjacent and in said contact with a heater of said humidifier gases delivery apparatus.

In a still further aspect the invention consists in a humidifier chamber for use with a gases humidification apparatus comprising:

a container, with a surrounding wall and top, and an open bottom,

a heat conductive base enclosing said open bottom of said container,

a gases inlet to said container,

a gases outlet to said container,

said gases inlet and said gases outlet facing the same direction, not being upwards, such that

said humidifier chamber may make operable engagement with a heater base in a single motion,

and fluid connections with said gases outlet and said gases inlet, being also made in said single motion.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

Two preferred embodiments of the present invention will now be described with reference to the drawings.

FIG. **1** is a perspective view of a water chamber and CPAP machine according to the first preferred embodiment of the present invention showing the water chamber **2** separated from the CPAP machine **1** and an arrow **43** indicating the path of air flow through the connection manifold of the CPAP machine and chamber.

FIG. **2** is a perspective view of a water chamber and CPAP machine according to the first preferred embodiment of the present invention showing the water chamber **2** engaged with the CPAP machine **1** as in use and an arrow indicating the exit path of air flow through the conduit connection manifold **9**.

FIG. **3** is a perspective view of a water chamber and humidifier base according to the second preferred embodiment of the present invention showing the water chamber **10** engaged in the connection manifold **23** of the heater base as in use.

FIG. **4** is a perspective view of a CPAP machine and water chamber according to an alternative embodiment of the present invention.

FIG. **5** is a perspective view of a water chamber of the present invention showing hidden detail of the inlet and outlet extension tubes.

FIG. **6** is a sectioned side view of the water tube of FIG. **5** section through a mid-line of the outlet extension tube with the intended water level shown hatched.

FIG. **7** is a sectioned side view of the water chamber of FIG. **5** sectioned through a mid-line of the chamber with the water level of the chamber when tilted shown hatched.

FIG. **8** is a perspective view of an inlet/outlet extension tube according to a preferred embodiment of the present invention showing snap-fit protrusions and locating/locking means.

FIG. **9** is a front view of a water chamber of the present invention showing the flanges and notches which co-operate with the extension tubes detailed in FIG. **8**.

FIG. **10** is a perspective view of an outlet extension tube according to a preferred embodiment of the present invention showing the air bleed slot.

FIG. **11** is a perspective view of the CPAP machine of FIG. **2**.

FIG. **12** is a perspective view of the humidifier base of FIG. **3**.

DETAILED DESCRIPTION

Two preferred embodiments of the present invention will now be described in detail.

Referring to FIGS. **1** and **2**, a first preferred embodiment of a CPAP machine and corresponding water chamber is shown. A water chamber having a gases inlet port **5** and gases outlet port **6** is shown with a portable CPAP machine, wherein the CPAP machine is adapted to receive slide-on chambers and which makes connection to the gases inlet/outlet ports of the water chamber through a connection manifold. Connection of the gases inlet and gases outlet ports are made to the connection manifold **8** of the CPAP machine in the same slide-on motion. The connection manifold also provides an auxiliary outlet connection port **9** suitable for receiving a flexible respiratory conduit to deliver humidified air to a patient.

The CPAP machine includes a heater base in a chamber receiving bay **47** to heat the water chamber, and a securing means for securing the water chamber to the CPAP machine. The securing means is provided by a securing latch **19** arid a slot **17** around the periphery and of the chamber receiving bay **47**. The slot co-operates with a flange **18** around the base of the water chamber to secure the chamber when in use. The securing latch **19** operates to prevent removal of the chamber once it has been engaged. The securing means and connection manifold are arranged with a parallel axis of operation such that connection of the chamber inlet and outlet ports **5** & **6**, to the connection manifold **8** is achieved as well as securing of the chamber into the CPAP machine in the same slide-on motion.

The latch **19**, having a locking position and a release position, is biased toward the locking position which prevents removal of the chamber from the CPAP machine. The front face of the latch is shaped such that during the single slide-on motion employed to fit the water chamber to the CPAP machine the flange **18** urges the securing latch **19** into the release position and allows the water chamber to be properly fitted. Once the water chamber is properly seated on the heater base and the inlet **5** and outlet **6** is properly engaged with the connection manifold **8**, the flange **18** and base of the chamber will no longer be in contact with the securing latch **19**. This allows the securing latch biasing means to urge the latch into the locking position and prevent the water chamber from being removed as shown in FIG. **2**.

Preferably the connection manifold **8** includes a passage which receives airflow from the blower and directs it into the water chamber **2**, as well as a passage which directs airflow received via the water chamber outlet port **6**, to the CPAP patient outlet port **9**. The connection passage connecting the manifold inlet port **7**, to the manifold patient outlet port **9** is shown in hidden detail **48** in FIG. **1**. Preferably the connection manifold **8** of the present invention is removable to aid cleaning and/or sterilisation of the passages. In one preferred embodiment the above connection passages are internal to the connection manifold **8** as illustrated in FIGS. **1** and **2**.

In use air from the CPAP machine blower exits through outlet port **4**, and enters the chamber **2** through inlet port **5**. Air entering the chamber is humidified by the evaporation of water from the water source in the bottom of the chamber before leaving the chamber through the patient outlet port **6**. Humidified air from the outlet port **6** is received into the connection manifold of the CPAP machine **8** via the inlet port **7**. The connection manifold **8** directs air to the outlet port **9** which is adapted to connect with a flexible conduit connector for delivery to a patient. An advantage obtained from the breathing conduit connection **9** being located on the body of the CPAP machine and not connected to the top of the water chamber directly, is that complete connection or disconnection of the water chamber from the CPAP system can be achieved with a single slide-on or slide-off motion. This feature makes removal of the water chamber for refilling considerably simpler.

A further advantage is obtained when additional electrical or pneumatic connections are required. The use of heated conduits requires electrical wiring connectors between the conduit and humidified air source while an additional pneumatic connection may be used for pressure feedback or measurement. In the present invention the connector which includes an additional electrical and/or pneumatic connection **54** for the conduit is integral to the connection manifold of the CPAP machine **8** and therefore allows the disposable water chamber to remain as simple as possible.

Referring to FIG. **3**, a second preferred embodiment of an in-line humidifier and corresponding water chamber is shown. A water chamber having a gases inlet port **11** and gases outlet port **12** is shown with an in line humidifier, wherein the humidifier is adapted to receive slide-on chambers and which makes connection to the gases inlet/outlet ports of the water chamber through a connection manifold **23**. Connection of the gases inlet and gases outlet port is made through the connection manifold **23** of the humidifier in the same slide-on motion. The connection manifold has an auxiliary inlet port **16** suitable for connection of a flexible conduit for delivery of airflow to the humidifier and an auxiliary patient outlet port **14** suitable for receiving flexible respiratory conduits to receive the humidified air flow.

Preferably the connection manifold **23** includes a passage **49** which receives airflow from the inlet conduit through inlet port **16** and directs it into the water chamber inlet port **11** through manifold outlet port **15**. Preferably the connection manifold **23** also includes a passage **50** which receives airflow from the water chamber outlet port **12**, via manifold inlet port **13** and directs it to the manifold patient outlet port **14**. The connection passages **49** and **50** are shown in hidden in FIG. **3**. Preferably the connection manifold **23** of the present invention is removable to aid cleaning and/or sterilisation of the passages. Preferably the connection passages are internal to the connection manifold **23**.

The humidifier includes a heater base to heat the water chamber and a securing means for securing the water chamber to the humidifier. The securing means is provided by a securing latch **22** and a slot **21** around the periphery and of the chamber receiving bay. The slot co-operates with a flange around the base of the water chamber **10** to secure the chamber when in use, while the securing latch operates to prevent removal of the chamber once it has been engaged. The securing means and connection manifold are arranged such that connection of the chamber inlet and outlet ports **11** and **12**, to the connection manifold **23** is achieved at the same time as securing of the chamber into the humidifier in the same slide-on motion. The latch **22**, having a locking position and a release position, is biased toward the locking position which prevents removal of the chamber from the humidifier. The front face of the latch **22** is shaped such that during the single slide-on motion employed to fit the water chamber to the humidifier the flange urges the securing latch **22** into the release position and allows the water chamber **10** to be properly fitted. Once the water chamber is properly seated on the heater base and the inlet **11** and outlet **12** is properly engaged with the connection manifold **23**, the flange and base of the water chamber will no longer be in contact with the securing latch **22** This allows the securing latch biasing means to urge the latch into the locking position and prevent the water chamber from being removed.

In use the humidifier inlet port **16** receives air flow through a flexible conduit. Air leaves the connection manifold **23** through the outlet port **15** and enters the water chamber **10** through the chamber inlet port **11**, where it is humidified by the evaporation of water from the water supply. Humidified air leaves the water chamber via outlet port **12**, enters the humidifier connection manifold inlet port **13**, finally exiting through the patient outlet port **14** into a breathing conduit for delivery to a patient. An advantage obtained by having both the inlet **16** and outlet **14** which connect to conduits, integral to the body of the humidifier and not part of the water chamber directly, is that complete connection/disconnection of the water chamber **10** from the humidifier base can be achieved with a single slide-on/off motion. This feature makes removal of the water chamber for refilling considerably simpler.

In a similar manner to the first preferred embodiment of a CPAP machine, a further advantage obtained from the configuration of the second preferred embodiment, arises when an additional electrical or pneumatic connection is required. The inlet and/or outlet connectors including an electrical and/or pneumatic connection **54** for the conduit are integral to the connection manifold of the humidifier and therefore allow the disposable water chamber to remain as simple as possible.

A number of alternative variations of the first and second preferred embodiments are envisaged and will now be described. For example, a further embodiment of the present invention is envisaged to deliver humidified gases from the water chamber to a patient via a flexible breathing conduit. This alternative embodiment is shown in FIG. **4**. An elbow tube **51** having an inlet end and an outlet end is provided to receive humidified gases from the water chamber and direct humidified gases into a flexible breathing conduit for delivery to a patient. In this alternative preferred embodiment the CPAP machine housing is provided with a recess **52** for receiving and securing the elbow tube. For example the recess **52** may include a neck or constriction that is above the elbow **51** when elbow **51** is in place. The neck holds the elbow in place under normal usage, but the elbow can be forcibly removed when required. When secured in position, an inlet **53** of the elbow tube **51** is positioned to make a fluid connection to the outlet **6** of the water chamber in the same slide on motion. In this alternative embodiment the outlet elbow may be part of the termination of the breathing tube instead of an internal part of the connection manifold as previously described. An advantage of this alternative embodiment is that all the parts in contact with condensation are removable for cleaning or sterilisation. This embodiment also retains the advantage of an engagable/disengagable water chamber in a single slide on/off motion. This embodiment may also include additional electrical or pneumatic connections **54** for making a connection between the CPAP machine and a conduit connector, enabling this alternative to retain the advantages of the previously described embodiments. While FIG. **4** shows this alternative preferred embodiment of the present invention applied to a CPAP machine it is envisaged that this embodiment may also be applied in an analogous manner to an inline humidifier such as that described in the second embodiment of the present invention and pictured in FIG. **3**.

An alternative embodiment of the present invention is envisaged wherein a water chamber and heater base are par-

tially or fully enclosed in a housing. The housing includes a connection manifold consisting of at least one gases inlet and at least one gases outlet connection port being adjacent and aligned, which in use transport gases to and/or from the water chamber. A second housing is provided with complementary inlet and outlet connections for registration with the connection manifold. The second housing is adapted to engage with the first housing making all the necessary gases and electrical connections in the same slide-on motion and preferably includes a securing means. The second housing may include an integral air blower, and a patient conduit outlet port in the case of a CPAP embodiment. Or in the case of an in-line humidifier embodiment, the second housing may include two conduit ports. The first conduit port in use receiving air from a source and the second conduit port delivering humidified air to a patient. The above described embodiment has the advantage that all necessary flexible conduit connections are made on the second housing. This enables the water chamber and/or enclosing housing to be removed/engaged in the same slide-off/on motion making refilling of the chamber simpler.

In the first and second preferred embodiments of the present invention, tubular protrusions are provided for making a connection between the humidifier apparatus and a water chamber in order to deliver gases to the chamber and receive humidified gases from the chamber. Preferably the tubular protrusions also include a resilient boot in order to provide an improved seal between the water chamber and the protrusions.

A further embodiment of the present invention is envisaged wherein the connections between the apparatus manifold and the water chamber are not provided side by side as described in the first and second embodiment of the present invention but rather are provided one within the other, for example the inlet and outlet may be coaxial. Such a configuration would enjoy the same advantages as the configurations described in more detail in the first and second embodiments of the present invention. It is also envisaged that such connections may also include similarly configured tubes for providing pressure measurements or pressure feedback.

While the above preferred embodiments describe male/female type connectors wherein the water chamber has two female connectors for mating with corresponding male connectors of the apparatus manifold, it is envisaged that many variations will present themselves to those skilled in the art without departing from the spirit of the present invention. For example the water chamber may be provided with two male connectors while the apparatus manifold is provided with corresponding female connectors, or the water chamber may be provided with one male and one female connector for connecting to the corresponding male and female connectors of the apparatus manifold. Further it is envisaged that connectors of an androgynous nature may be provided for making connection between the water chamber and the apparatus manifold wherein each connector may include both male type protruding portions and female type recess portions. Such connections may be particularly advantageous when the inlet and outlet is provided one within the other.

With reference to the first and second preferred embodiments of the present invention, some common features of a water chamber suitable for use with either preferred embodiment will now be described in more detail.

The chamber as shown in FIG. **5** is constructed from an open bottomed plastic container enclosed by a heat conductive base **24**, and includes a horizontally aligned gases inlet **27** and a parallel gases outlet **28**. It is envisaged that other configurations of the present invention are possible where the slide-on direction employed to fit the water chamber is not horizontal but at an angle from the horizontal or vertical. In such cases, the gases inlet **27** arid outlet **28**, are preferably parallel and aligned with the direction of the intended slide-on motion to allow mating of the chamber inlet/outlet ports and the connection manifold.

The water chamber of the present invention preferably includes an inlet extension tube **30**, and an outlet extension tube **31**, extending inwardly into the chamber interior from the periphery of the chamber wall and preferably having a generally tapering body. The inlet extension tube **30** and the outlet extension tube **31** are preferably moulded from the same clear thermoplastic material as the chamber shell **26**. The inclusion of inlet/outlet extension tubes has been found to significantly reduce noise produced by the airflow around the chamber. Preferably at least one extension tube has an air bleed aperture to aid filling of the chamber with the chamber tipped up. The air bleed is preferably located in the top surface of the extension tube and preferably toward the end of the extension tube which is connected to the chamber wall. Referring to FIG. **6**, preferably the air bleed aperture **33** is positioned such that when the tank is tipped up for filling, the air bleed valve height corresponds with the preferred fill height **32** for the water chamber. This feature aids in preventing overfilling of the water chamber.

Additionally, with reference to FIG. **7**, the extension tubes **30** and **31** may act as a weir against water flow back through the gases inlet and gases outlet, upon tilting of the chamber as shown by water level line **44**. If present, preferably the air bleed aperture **33** is present only on the outlet extension tube **31** and not present in the inlet extension tube **30**. This prevents water back-flow through the inlet port **27** occurring upon tilting of the chamber.

The present invention may further include a downwardly extending central baffle or rib located between the inlet and outlet extension tubes to ensure against gases short circuiting the chamber by flowing directly from the exit of the inlet extension tube **34**, to the entry of the outlet extension tube **35**. With the baffle the gases are forced to follow a more tortuous path ensuring adequate humidification during their journey through the chamber.

In use air is received into the chamber via inlet port **27** and travels down the inlet extension tube **30**. On exiting the inlet extension tube **30** air enters the chamber where it is humidified by the evaporation of water from the water supply. Humidified air flows from the chamber through the outlet extension tube **31** and exits through outlet port **28**. The above described flow path is illustrated in FIG. **5** by the arrow **45**.

Although the preceding description gives details of preferred embodiments having parallel and adjacent circular inlet/outlet ports, it is envisaged that other configurations are possible without departing from the spirit of the invention. For example the inlet/outlet ports of the chamber and connection manifold may have a non-circular cross section and not be symmetrical. Further it is possible that the position of the inlet port with respect to the outlet may take one of many alternative configurations. For example the ports and there corresponding connections may also be co-axial or off-set, one inside the other.

Referring to FIGS. **8-10**, for ease of assembly the inlet and outlet extension tubes are preferably provided as a snap fit to their respective water chamber inlet or outlet, so that they can be pushed into the chamber through the inlet or outlet and, upon application of sufficient force, snap into a substantially watertight and secure condition.

To this end the inlet **27** and outlet **28** ports of the water chamber may be provided with an inwardly perpendicularly extending annular flange **36** at the inner end thereof and the inlet/outlet extension tubes **38** may include similar perpendicularly outwardly extending flanges **37** from one end of the generally tapering tubular body **46**. The flanges act together as sealing flanges in the fitted and assembled condition. To retain the extension tubes in the assembled condition, against

both translational and rotational movement several securing mechanisms may be provided. In each case the securing mechanisms may be provided on either of the inlet/outlet (of the chamber) or the inlet/outlet extension tube. However it is preferred that they be on the extension tubes, as both components are intended for injection moulding and injection moulding of certain protrusions on the inner surface of the chamber inlet/outlet would be considerably more difficult than on the outer surface of the extension tubes. To secure the tubes against translational movement, and in a sealing condition between the sealing flanges, a plurality of retaining clip protrusions **39** may be provided spaced around the circumference of the tubular body of the extension tubes which cooperate with the inlet/outlet flange **36**. Particularly for ease of manufacture, and ensuring a simple two part injection mould, a notch **42** is allowed in the flange **37** of the extension tubes **38** adjacent the protrusion **39**.

To retain the extension tubes against rotational movement when snap fitted into location, one or more locating protrusions **40** may be provided circumferentially distributed on the outer surface of the tubular body adjacent and contiguous with the outwardly and perpendicularly extending flange **37**. The locating protrusions **40** are preferably generally tapered in both the circumferential and axial direction. Complementary notches **41** are provided in the inwardly extending flanges **36** of the chamber inlet and outlet. In fitting the extension tubes **38** the protrusions **40** are aligned with the notches **41**, and upon full insertion of the tubes, the protrusions **40** enter into a tight frictional fit with the notches **41** ensuring substantial if not complete sealing. It will be appreciated that the mechanism employed to ensure proper location and sealing of the extension tubes into the water chamber may take many forms. Many alternatives will suggest themselves to persons skilled in the art such as glued joints, various forms of plastic welding and various configurations of clipping means and protrusions. The above description is of one particular preferred embodiment and is not meant to be in any way limiting.

It will be readily appreciated that the construction of the water chamber as described is simple to manufacture and each of the plastic components is itself capable of simple injection moulding. Consequently a water chamber according to the present invention is, while providing significant advantages, not significantly more expensive than existing chambers.

The invention claimed is:

1. An apparatus for use in humidified gases delivery treatment comprising:

a housing,

a removable humidification chamber with a base,

a gases line inlet in said housing to receive pressurised gases from a pressurised gases source, said gases line inlet adapted to make a separable fluid connection with a breathing conduit,

a gases outlet in said housing in fluid connection with said gases line inlet, adapted to make a separable fluid connection with an inlet of said humidification chamber in order to provide gases flow into said humidification chamber,

a humidified gases return in said housing, adapted to make a separable fluid connection with an outlet of said humidification chamber in order to receive humidified gases from said humidification chamber,

a gases line outlet in said housing, in fluid connection with said humidified gases return, adapted to make fluid connection with or in fluid connection with a breathing conduit for delivery of humidified gases to a patient,

a chamber heater in said housing for vaporising liquid water in said humidification chamber in order to provide water vapour to gases flow passing through said humidification chamber,

said housing adapted to accommodate a humidification chamber, said humidification chamber being removable and engagable with said housing via a single motion, said single motion of engagement urging the base of said humidification chamber adjacent and in contact with said chamber heater, said single motion also making or breaking said separable connections between said gases outlet and said humidification chamber inlet, and said humidified gases return and said humidification chamber outlet.

2. An apparatus for use in humidified gases delivery treatment as claimed in claim **1** wherein

said gases outlet and said inlet of a said humidification chamber have between them first complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of the male and female connectors,

said humidified gases return and said outlet of a said humidifier have between them second complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of a male and female connectors said preferred insertion direction of said first connectors being the same as said preferred insertion direction of said second connectors, and being the same as at least the direction of a terminal part of said single motion.

3. An apparatus for use in humidified gases delivery treatment as claimed in claim **2** wherein said inlet of a said humidification chamber and said outlet of a said humidification chamber are each a female port, and

said gases outlet and said humidified gases return are each a resilient tubular projection fitting within respective female ports with said humidification chamber engaged.

4. An apparatus for use in humidified gases delivery treatment as claimed in claim **3** wherein said resilient tubular projections of said gases outlet and said humidified gases return have parallel axis of extension, said chamber heater is a substantially planar heating plate, and said axis of extension of said tubes are at least substantially parallel with said direction of single motion.

5. An apparatus for use in humidified gases delivery treatment as claimed in claim **1** wherein said gases line outlet includes a connector for receiving a breathing hose and at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electric or pneumatic connectors.

6. A humidifier chamber for use with a gases humidification apparatus, the humidifier chamber comprising:

a container defining a water chamber having an aperture in the bottom, with a surrounding wall and top,

a heat conductive base enclosing said aperture in the bottom of said water chamber,

a gases inlet to said container adapted to receive a substantially horizontal flow of gases into said container,

a gases outlet from said container adapted to deliver a substantially horizontal flow of gases out of said container,

said gases inlet and said gases outlet being parallel and aligned, such that said humidifier chamber may make operable engagement with a humidified gases delivery apparatus in a single motion, and

at least one extension tube extending horizontally inward into said humidifier chamber from an inner periphery of said gases inlet and/or gases outlet,

wherein said single motion disposes said heat conductive base adjacent a heater in said humidified gases delivery apparatus.

7. A humidifier chamber as claimed in claim **6**, wherein said gases inlet and said gases outlet are each a female port, and

said humidifier chamber is generally cylindrical including a cylindrical wall, and said female ports open out to the cylindrical wall near the top of the chamber.

8. A humidifier chamber as claimed in claim **7** wherein at least a terminal part of said single motion is parallel to the said base of said chamber, and said terminal part of said single motion completes connections with said gases inlet and said gases outlet.

9. A humidifier chamber as claimed in claim **6**, wherein the at least one extension tube comprises an elongate inlet extension tube extending into said humidifier chamber from an inner periphery of said gases inlet, and an elongate outlet extension tube extending into said humidifier chamber from the inner periphery of said gases outlet.

10. A humidifier chamber as claimed in claim **9** wherein, said outlet extension tube includes an air bleed aperture, said air bleed aperture being located in the top of said outlet extension tube, and located toward the end of the outlet extension tube adjacent said gases outlet.

11. An apparatus for use in a humidified gases delivery treatment as claimed in claim **1** wherein said housing includes a connection manifold.

12. An apparatus for use in a humidified gases delivery treatment as claimed in claim **11** wherein said connection manifold comprising:

said gases line inlet adapted to make a fluid connection with a breathing conduit in order to receive pressurised gases,

said gases outlet adapted to make a separable fluid connection with an inlet of a humidification chamber in order to provide gases into said humidification chamber,

said humidified gases return adapted to make a separable fluid connection with an outlet of said humidification chamber in order to receive humidified gases from said humidification chamber,

said gases line outlet in fluid connection with said gases return, said gases line outlet adapted to make a fluid connection with a breathing conduit for delivery of humidified gases to a patient,

said separable connections being made or broken by a single motion of said humidifier chamber being placed adjacent to said manifold.

13. An apparatus for use in a humidified gases delivery treatment as claimed in claim **12** wherein said manifold includes a passage between said gases line inlet and said gases outlet.

14. An apparatus for use in a humidified gases delivery treatment as claimed in claim **12** wherein said manifold includes a passage between said humidified gases return and said gases line outlet.

15. An apparatus for use in a humidified gases delivery treatment as claimed in claimed claim **13** or **14** wherein said passages arc internal to said connection manifold.

16. An apparatus for use in a humidified gases delivery treatment as claimed in claim **11**, wherein said manifold is removable from said housing.

17. An apparatus for use in a humidified gases delivery treatment as claimed in claim **1** wherein said humidified gases return and said gases line outlet are separable from said apparatus.

18. An apparatus for use in a humidified gases delivery treatment as claimed in claim **17** wherein said apparatus includes an elbow tube having an inlet and an outlet, said elbow tube inlet comprising said humidified gases return and said elbow tube outlet comprising said gases line outlet.

19. An apparatus for use in a humidified gases delivery treatment as claimed in claim **18** wherein said housing includes a recess to accommodate and engage said elbow tube, said recess including a constriction within it, said constriction holding said elbow tube in said recess.

20. A humidifier chamber as claimed in claim **9** wherein said opening of said elongate inlet extension tube faces a direction transverse to an axis of said elongate inlet extension tube, and said opening of said elongate outlet extension tube face a direction transverse to an axis of said elongate outlet extension tube.

21. A humidifier chamber as claimed in claim **20** wherein said transverse direction is not downwards.

22. A humidifier chamber as claimed in claim **6**, wherein said gases inlet and said gases outlet are parallel to each other.

23. A humidifier chamber as claimed in claim **6**, wherein said at least one extension tube is releasably coupled to said container.

24. A gas humidification apparatus comprising:

a humidification chamber comprising a base, and

a housing comprising:

a source gases outlet adapted to make a separable fluid connection with an inlet of said humidification chamber in order to provide gases flow into said humidification chamber,

a humidified gases inlet adapted to make a separable fluid connection with an outlet of said humidification chamber in order to receive humidified gases from said humidification chamber,

a humidified gases outlet in fluid communication with said humidified gases inlet, said humidified gases outlet adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient, and

a heater configured to vaporize liquid water in said humidification chamber to provide water vapor to gases flowing through said humidification chamber,

wherein said housing is adapted to accommodate said humidification chamber, said humidification chamber being removable and engageable with said housing via a single motion, wherein said single motion of engagement disposes the base of said humidification chamber adjacent said heater, said single motion also making or breaking said separable connections between said source gases outlet and said humidification chamber inlet, and said humidified gases inlet and said humidification chamber outlet.

25. A gas humidification apparatus as claimed in claim **24**, wherein the housing further comprises a source gases inlet for receiving gases from the surroundings or a gases source line.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	: 8,091,547 B2
APPLICATION NO.	: 11/428704
DATED	: January 10, 2012
INVENTOR(S)	: Mohammad Thudor et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page (Primary Examiner), line 1, please change "Justin" to --Justine--.

At column 2, line 56, please change "outlet," to --outlet.--.

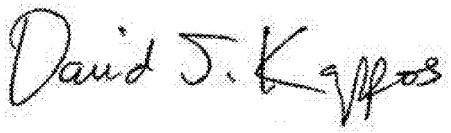
At column 3, lines 8-23, below "apparatus." please delete "In a still further aspect the ..... being also made, in said single motion.".

At column 4, line 32, please change "arid" to --and--.

At column 7, line 67, please change "arid" to --and--.

At column 10, line 61, in Claim 6, after "being" please delete "parallel and".

Signed and Sealed this
Nineteenth Day of June, 2012



David J. Kappos
Director of the United States Patent and Trademark Office

EXHIBIT 8

US007111624B2

(12) **United States Patent**
Thudor et al.

(10) **Patent No.: US 7,111,624 B2**
(45) **Date of Patent: Sep. 26, 2006**

(54) **APPARATUS FOR DELIVERING HUMIDIFIED GASES**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 518 days.

(21) Appl. No.: **10/246,328**

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(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation-in-part of application No. 09/808,567, filed on Mar. 14, 2001, now Pat. No. 6,918,389.

(30) **Foreign Application Priority Data**

Mar. 21, 2000 (NZ) 503495

(51) **Int. Cl.**
A61M 15/00 (2006.01)
A62B 7/00 (2006.01)

(52) **U.S. Cl.** **128/203.16**; 128/204.17; 128/204.18; 128/203.17

(58) **Field of Classification Search** ..... 128/203.12, 128/203.17, 203.16, 203.26, 203.27, 204.17; 604/23; 392/386, 390; 261/DIG. 65, DIG. 4, 261/DIG. 515
See application file for complete search history.

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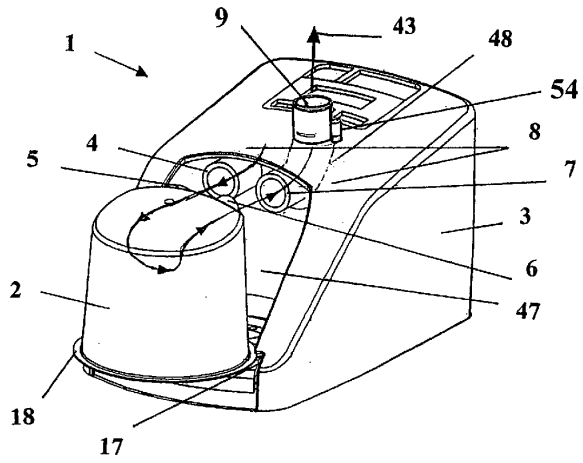
(57) **ABSTRACT**

An apparatus for delivering humidified gases has a connection manifold adapted to connect with inlet and outlet ports of a slide on water chamber in a single slide on motion. Connection of the gases inlet and gases outlet ports as well as any additional electrical and/or pneumatic connections are all made in the same slide on motion. The water chamber may include inwardly extending elongate extension tubes with one of the extension tubes having an air bleed aperture to aid filling of the chamber.

7 Claims, 7 Drawing Sheets



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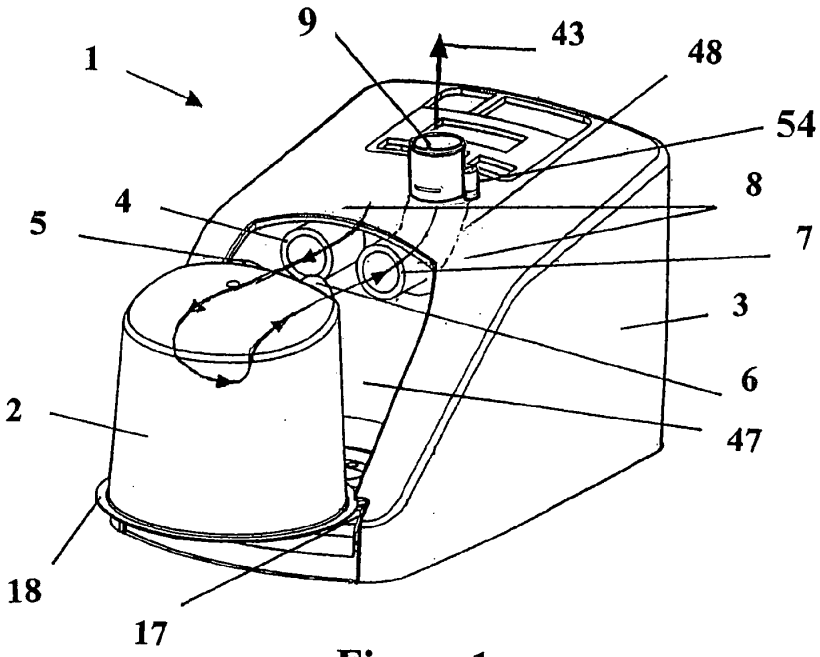
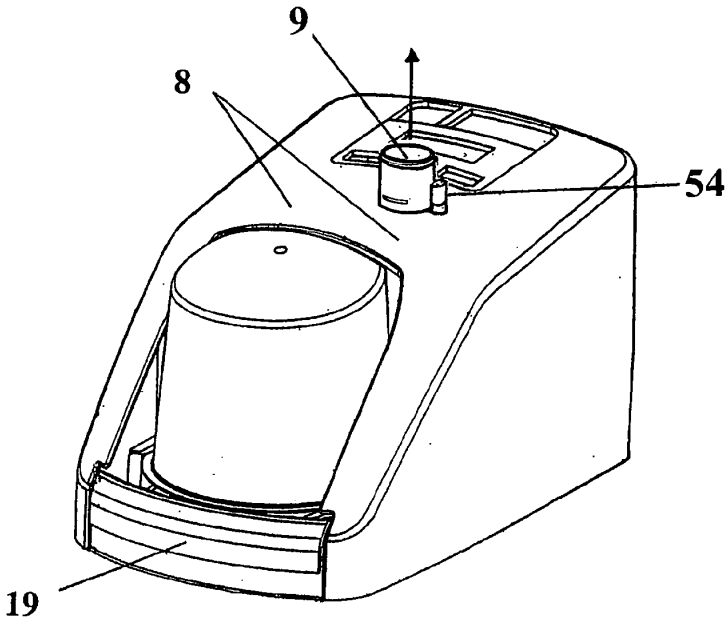


Figure 1



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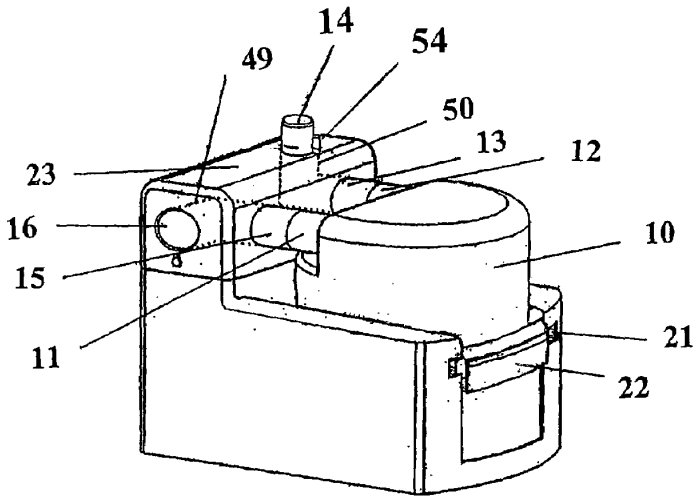

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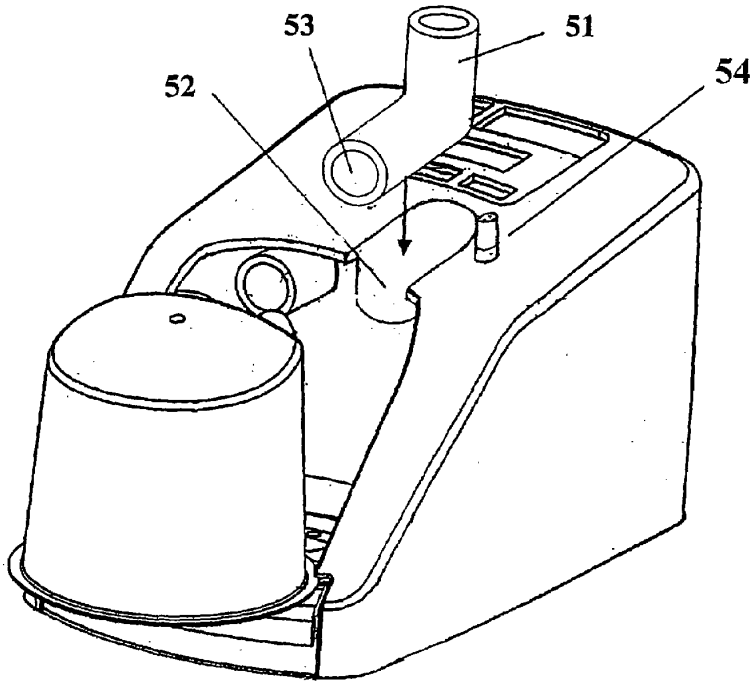

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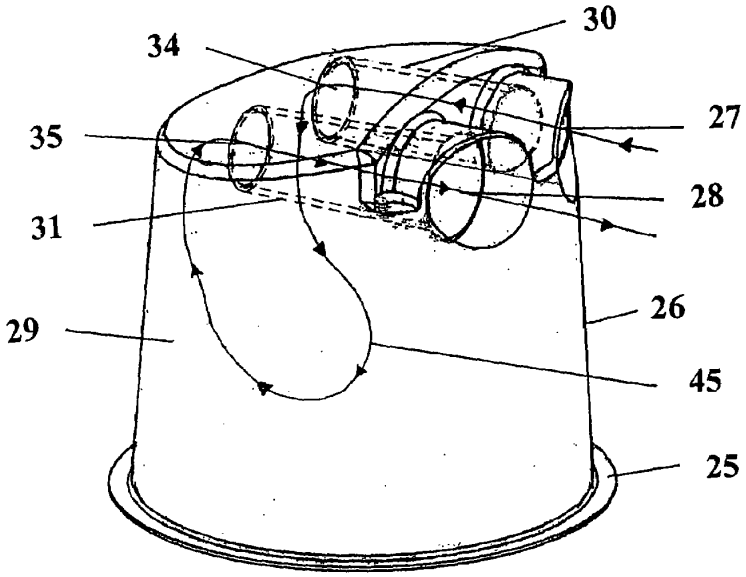

Figure 5

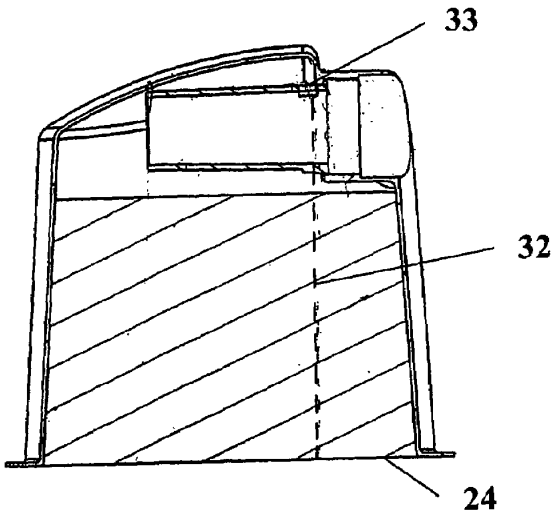

Figure 6

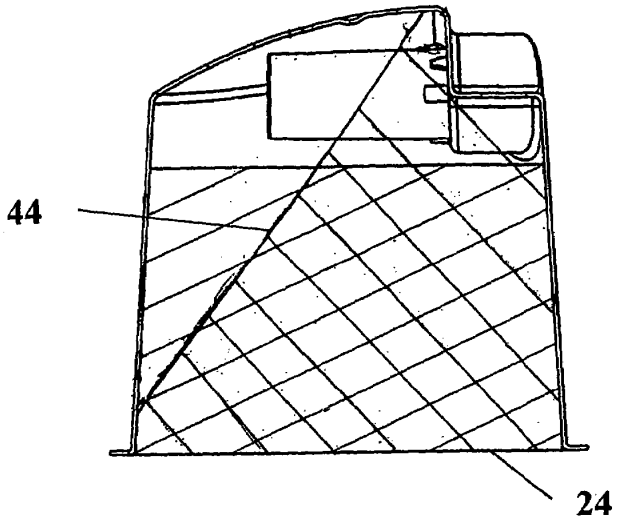

Figure 7

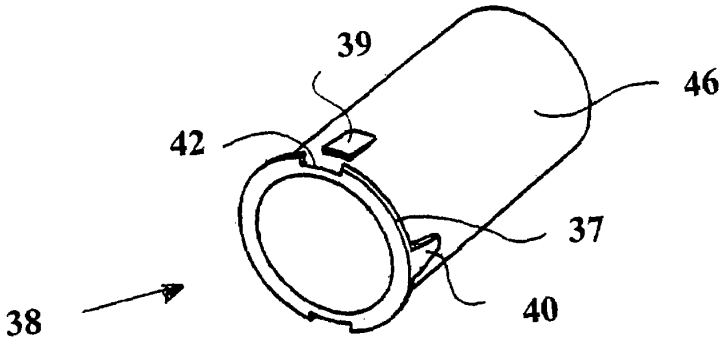

Figure 8

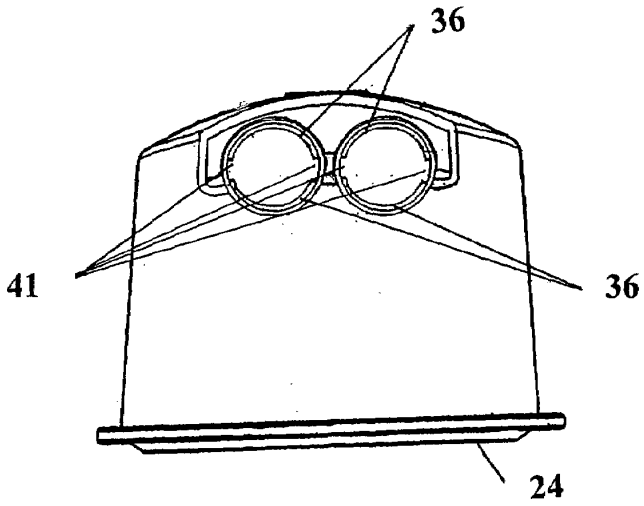

Figure 9

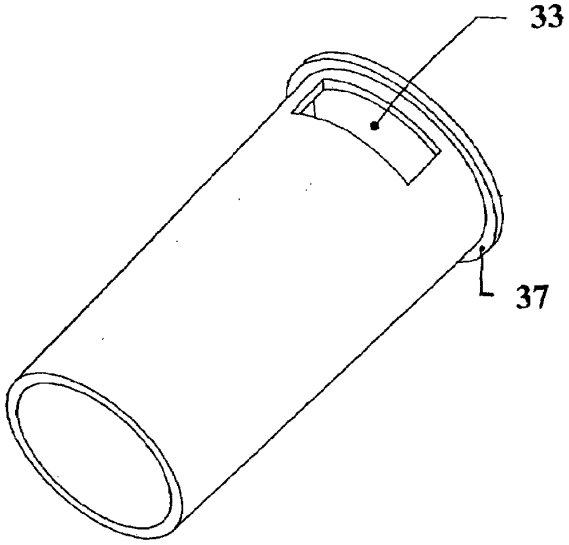

Figure 10

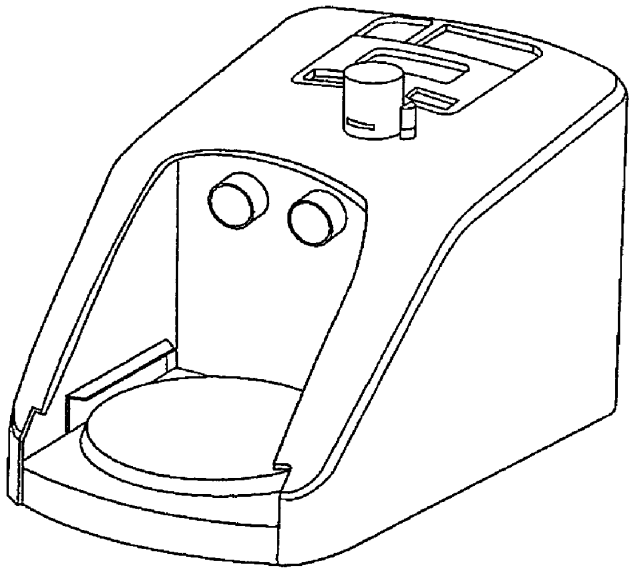

Figure 11

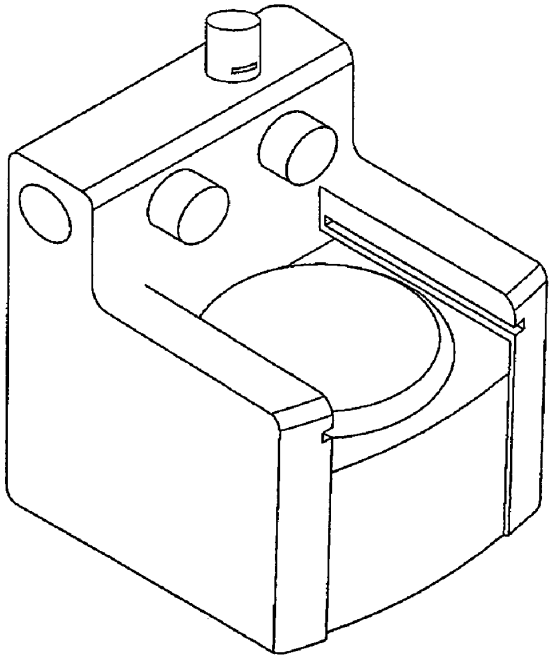

Figure 12

APPARATUS FOR DELIVERING HUMIDIFIED GASES

This is a Continuation-In-Part of U.S. patent application Ser. No. 09/808,567 filed on Mar. 14, 2001 now U.S. Pat. No. 6,918,389.

BACKGROUND TO THE INVENTION

i) Field of the Invention

The present invention relates to apparatus for delivering humidified gases. In particular it relates to a humidifier arrangement for use in stand alone humidifiers used for example in providing respiratory assistance to patients receiving mechanical ventilation or respiratory support and/or integrated humidifiers included for example in consumer CPAP delivery devices.

ii) Summary of the Prior Art

Humidification systems are known which include a heater base and a disposable humidifier chamber which is fitted onto the heater base and within which a supply of water can be heated by the heater base. Air enters the humidifier chamber through an inlet air port in the roof of the chamber where it is humidified by the evaporation of water from the water supply before leaving the chamber through an exit port in the roof of the humidifier chamber.

Humidifier chambers of this type are also now used in compact and portable ventilation machines, for example machines intended for the home treatment of obstructive sleep apnoea (CPAP machines). Where the humidifier base is adapted for use with slide-on humidifier chambers, and the connection of the chamber to the machine is accomplished with a single sliding movement, the inlet air port is provided horizontally through the side of the chamber. Air enters the humidifier chamber through the inlet air port and the humidified air leaves the humidifier chamber into a breathing conduit through an exit port in the top of the humidifier chamber.

A disadvantage of these configurations is the need to disconnect the patient breathing conduit from the top of the humidifying chamber in a separate operation before removal of the chamber for the purpose of refilling. A further disadvantage of these configurations is that separate electrical wiring connections are required to make use of a heated respiratory conduit.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an apparatus for delivering humidified gases which at least goes some way towards overcoming the above disadvantages or which will at least provide the public with a useful choice.

In a first aspect the invention consists in an apparatus for use in humidified gases delivery treatment comprising:

a housing,

a pressurised gases outlet in said housing adapted to make fluid connection with an inlet of a humidifier in order to provide gases flow to a said humidifier,

a humidified gases return in said housing, adapted to make fluid connection with an outlet of a said humidifier in order to receive humidified gases from said humidifier,

a patient outlet in said housing, in fluid connection with said humidified gases return in order to receive humidified gases from said humidified gases return and provide humidified gases to said patient outlet, said patient outlet being in fluid connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient.

In a further aspect the invention consists in an apparatus for use in humidified gases delivery treatment comprising:

a housing,

a pressurised gases supply within said housing,

a pressurised gases outlet in said housing in fluid connection with said pressurised gases supply and adapted to make fluid connection with an inlet of a humidifier in order to provide gases flow to a said humidifier,

a humidified gases return in said housing, adapted to make fluid connection with an outlet of a said humidifier in order to receive humidified gases from said humidifier,

a patient outlet in said housing, in fluid connection with said humidified gases return in order to receive humidified gases from said humidified gases return and provide humidified gases to said patient outlet, said patient outlet being in fluid connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient.

In a still further aspect the invention consists in an apparatus for use in humidified gases delivery treatment comprising:

a housing,

a gases line inlet in said housing to receive pressurised gases from a pressurised gases source, said gases line inlet adapted to make fluid connection with a breathing conduit,

a gases outlet in said housing in fluid connection with said gases line inlet, adapted to make fluid connection with an inlet of a humidification chamber in order to provide gases flow into a said humidification chamber,

a humidified gases return in said housing, adapted to make fluid connection with an outlet of a said humidification chamber in order to receive humidified gases from said humidification chamber,

a gases line outlet in said housing, in fluid connection with said humidified gases return, adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient,

a chamber heating means in said housing for vaporising liquid water in said humidification chamber in order to provide water vapour to gases flow passing through said humidification chamber,

said humidification chamber having a base, said chamber being removable and engagable with said housing via a single motion, said single motion of engagement urging the base of said humidification chamber adjacent and in contact with said chamber heating means, and

making a first fluid connection between said gases outlet and said humidification chamber inlet, and

making a second fluid connection between said humidified gases return and said humidification chamber outlet,

said first and second fluid connections being made in the direction of said single motion.

In a still further aspect the invention consists in a humidifier chamber for use with a gases humidification apparatus comprising:

a container, with a surrounding wall and top, and an open bottom,

a heat conductive base enclosing said open bottom of said container,

a gases inlet to said container,

a gases outlet to said container,

said gases inlet and said gases outlet facing the same direction, not being upwards, such that

said humidifier chamber may make operable engagement with a heater base in a single motion,

and fluid connections with said gases outlet and said gases inlet, being also made in said single motion.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

Two preferred embodiments of the present invention will now be described with reference to the drawings.

FIG. **1** is a perspective view of a water chamber and CPAP machine according to the first preferred embodiment of the present invention showing the water chamber **2** separated from the CPAP machine **1** and an arrow **43** indicating the path of air flow through the connection manifold of the CPAP machine and chamber.

FIG. **2** is a perspective view of a water chamber and CPAP machine according to the first preferred embodiment of the present invention showing the water chamber **2** engaged with the CPAP machine **1** as in use and an arrow indicating the exit path of air flow through the conduit connection manifold **9**.

FIG. **3** is a perspective view of a water chamber and humidifier base according to the second preferred embodiment of the present invention showing the water chamber **10** engaged in the connection manifold **23** of the heater base as in use.

FIG. **4** is a perspective view of a CPAP machine and water chamber according to an alternative embodiment of the present invention.

FIG. **5** is a perspective view of a water chamber of the present invention showing hidden detail of the inlet and outlet extension tubes.

FIG. **6** is a sectioned side view of the water tube of FIG. **5** section through a mid-line of the outlet extension tube with the intended water level shown hatched.

FIG. **7** is a sectioned side view of the water chamber of FIG. **5** sectioned through a mid-line of the chamber with the water level of the chamber when tilted shown hatched.

FIG. **8** is a perspective view of an inlet/outlet extension tube according a preferred embodiment of the present invention showing snap-fit protrusions and locating/locking means.

FIG. **9** is a front view of a water chamber of the present invention showing the flanges and notches which cooperate with the extension tubes detailed in FIG. **8**.

FIG. **10** is a perspective view of an outlet extension tube according to a preferred embodiment of the present invention showing the air bleed slot.

FIG. **11** is a perspective view of the CPAP machine of FIG. **2**.

FIG. **12** is a perspective view of the humidifier base of FIG. **3**.

DETAILED DESCRIPTION

Two preferred embodiments of the present invention will now be described in detail.

Referring to FIGS. **1** and **2**, a first preferred embodiment of a CPAP machine and corresponding water chamber is shown. A water chamber having a gases inlet port **5** and gases outlet port **6** is shown with a portable CPAP machine, wherein the CPAP machine is adapted to receive slide-on chambers and which makes connection to the gases inlet/outlet ports of the water chamber through a connection manifold. Connection of the gases inlet and gases outlet ports are made to the connection manifold **8** of the CPAP machine in the same slide-on motion. The connection manifold also provides an auxiliary outlet connection port **9** suitable for receiving a flexible respiratory conduit to deliver humidified air to a patient.

The CPAP machine includes a heater base in a chamber receiving bay **47** to heat the water chamber, and a securing means for securing the water chamber to the CPAP machine. The securing means is provided by a securing latch **19** and a slot **17** around the periphery and of the chamber receiving bay **47**. The slot co-operates with a flange **118** around the base of the water chamber to secure the chamber when in use. The securing latch **19** operates to prevent removal of the chamber once it has been engaged. The securing means and connection manifold are arranged with a parallel axis of operation such that connection of the chamber inlet and outlet ports **5** & **6**, to the connection manifold **8** is achieved as well as securing of the chamber into the CPAP machine in the same slide-on motion.

The latch **19**, having a locking position and a release position, is biased toward the locking position which prevents removal of the chamber from the CPAP machine. The front face of the latch is shaped such that during the single slide-on motion employed to fit the water chamber to the CPAP machine the flange **18** urges the securing latch **19** into the release position and allows the water chamber to be properly fitted. Once the water chamber is properly seated on the heater base and the inlet **5** and outlet **6** is properly engaged with the connection manifold **8**, the flange **18** and base of the chamber will no longer be in contact with the securing latch **19**. This allows the securing latch biasing means to urge the latch into the locking position and prevent the water chamber from being removed as shown in FIG. **2**.

Preferably the connection manifold **8** includes a passage which receives airflow from the blower and directs it into the water chamber **2**, as well as a passage which directs airflow received via the water chamber outlet port **6**, to the CPAP patient outlet port **9**. The connection passage connecting the manifold inlet port **7**, to the manifold patient outlet port **9** is shown in hidden detail **48** in FIG. **1**. Preferably the connection manifold **8** of the present invention is removable to aid cleaning and/or sterilisation of the passages. In one preferred embodiment the above connection passages are internal to the connection manifold **8** as illustrated in FIGS. **1** and **2**.

In use air from the CPAP machine blower exits through outlet port **4**, and enters the chamber **2** through inlet port **5**. Air entering the chamber is humidified by the evaporation of water from the water source in the bottom of the chamber before leaving the chamber through the patient outlet port **6**. Humidified air from the outlet port **6** is received into the connection manifold of the CPAP machine **9** via the inlet port **7**. The connection manifold **8** directs air to the outlet port **9** which is adapted to connect with a flexible conduit connector for delivery to a patient. An advantage obtained from the breathing conduit connection **9** being located on the body of the CPAP machine and not connected to the top of the water chamber directly, is that complete connection or disconnection of the water chamber from the CPAP system can be achieved with a single slide-on or slide-off motion. This feature makes removal of the water chamber for refilling considerably simpler.

A further advantage is obtained when additional electrical or pneumatic connections are required. The use of heated conduits requires electrical wiring connectors between the conduit and humidified air source while an additional pneumatic connection may be used for pressure feedback or measurement. In the present invention the connector which includes an additional electrical and/or pneumatic connection **54** for the conduit is integral to the connection manifold of the CPAP machine **8** and therefore allows the disposable water chamber to remain as simple as possible.

Referring to FIG. **3**, a second preferred embodiment of an in-line humidifier and corresponding water chamber is shown. A water chamber having a gases inlet port **11** and gases outlet port **12** is shown with an in line humidifier, wherein the humidifier is adapted to receive slide-on chambers and which makes connection to the gases inlet/outlet ports of the water chamber through a connection manifold **23**. Connection of the gases inlet and gases outlet port is made through the connection manifold **23** of the humidifier in the same slide-on motion. The connection manifold has an auxiliary inlet port **16** suitable for connection of a flexible conduit for delivery of airflow to the humidifier and an auxiliary patient outlet port **14** suitable for receiving flexible respiratory conduits to receive the humidified air flow.

Preferably the connection manifold **23** includes a passage **49** which receives airflow from the inlet conduit through inlet port **16** and directs it into the water chamber inlet port **11** through manifold outlet port **15**. Preferably the connection manifold **23** also includes a passage **50** which receives airflow from the water chamber outlet port **12**, via manifold inlet port **13** and directs it to the manifold patient outlet port **14**. The connection passages **49** and **50** are shown in hidden in FIG. **3**. Preferably the connection manifold **23** of the present invention is removable to aid cleaning and/or sterilisation of the passages. Preferably the connection passages are internal to the connection manifold **23**.

The humidifier includes a heater base to heat the water chamber and a securing means for securing the water chamber to the humidifier. The securing means is provided by a securing latch **22** and a slot **21** around the periphery and of the chamber receiving bay. The slot co-operates with a flange around the base of the water chamber **10** to secure the chamber when in use, while the securing latch operates to prevent removal of the chamber once it has been engaged. The securing means and connection manifold are arranged such that connection of the chamber inlet and outlet ports **11** and **12**, to the connection manifold **23** is achieved at the same time as securing of the chamber into the humidifier in the same slide-on motion. The latch **22**, having a locking position and a release position, is biased toward the locking position which prevents removal of the chamber from the humidifier. The front face of the latch **22** is shaped such that during the single slide-on motion employed to fit the water chamber to the humidifier the flange urges the securing latch **22** into the release position and allows the water chamber **10** to be properly fitted. Once the water chamber is properly seated on the heater base and the inlet **11** and outlet **12** is properly engaged with the connection manifold **23**, the flange and base of the water chamber will no longer be in contact with the securing latch **22** This allows the securing latch biasing means to urge the latch into the locking position and prevent the water chamber from being removed.

In use the humidifier inlet port **16** receives air flow through a flexible conduit. Air leaves the connection manifold **23** through the outlet port **15** and enters the water chamber **10** through the chamber inlet port **11**, where it is humidified by the evaporation of water from the water supply. Humidified air leaves the water chamber via outlet port **12**, enters the humidifier connection manifold inlet port **13**, finally exiting through the patient outlet port **14** into a breathing conduit for delivery to a patient. An advantage obtained by having both the inlet **16** and outlet **14** which connect to conduits, integral to the body of the humidifier and not part of the water chamber directly, is that complete connection/disconnection of the water chamber **10** from the humidifier base can be achieved with a single slide-on/off motion. This feature makes removal of the water chamber for refilling considerably simpler.

In a similar manner to the first preferred embodiment of a CPAP machine, a further advantage obtained from the configuration of the second preferred embodiment, arises when an additional electrical or pneumatic connection is required. The inlet and/or outlet connectors including an electrical and/or pneumatic connection **54** for the conduit are integral to the connection manifold of the humidifier and therefore allow the disposable water chamber to remain as simple as possible.

A number of alternative variations of the first and second preferred embodiments are envisaged and will now be described. For example, a further embodiment of the present invention is envisaged to deliver humidified gases from the water chamber to a patient via a flexible breathing conduit. This alternative embodiment is shown in FIG. **4**. An elbow tube **51** having an inlet end and an outlet end is provided to receive humidified gases from the water chamber and direct humidified gases into a flexible breathing condiut for delivery to a patient. In this alternative preferred embodiment the CPAP machine housing is provided with a recess **52** for receiving and securing the elbow tube. For example the recess **52** may include a neck or constriction that is above the elbow **51** when elbow **51** is in place. The neck holds the elbow in place under normal usage, but the elbow can be forcibly removed when required. When secured in position, an inlet **53** of the elbow tube **51** is positioned to make a fluid connection to the outlet **6** of the water chamber in the same slide on motion. In this alternative embodiment the outlet elbow may be part of the termination of the breathing tube instead of an internal part of the connection manifold as previously described. An advantage of this alternative embodiment is that all the parts in contact with condensation are removable for cleaning or sterilisation. This embodiment also retains the advantage of an engagable/disengagable water chamber in a single slide on/off motion. This embodiment may also include additional electrical or pneumatic connections **54** for making a connection between the CPAP machine and a conduit connector, enabling this alternative to retain the advantages of the previously described embodiments. While FIG. **4** shows this alternative preferred embodiment of the present invention applied to a CPAP machine it is envisaged that this embodiment may also be applied in an analogous manner to an inline humidifier such as that described in the second embodiment of the present invention and pictured in FIG. **3**.

An alternative embodiment of the present invention is envisaged wherein a water chamber and heater base are partially or fully enclosed in a housing. The housing includes a connection manifold consisting of at least one gases inlet and at least one gases outlet connection port being adjacent and aligned, which in use transport gases to and/or from the water chamber. A second housing is provided with complementary inlet and outlet connections for registration with the connection manifold. The second housing is adapted to engage with the first housing making all the

necessary gases and electrical connections in the same slide-on motion and preferably includes a securing means. The second housing may include an integral air blower, and a patient conduit outlet port in the case of a CPAP embodiment. Or in the case of an in-line humidifier embodiment, the second housing may include two conduit ports. The first conduit port in use receiving air from a source and the second conduit port delivering humidified air to a patient. The above described embodiment has the advantage hat all necessary flexible conduit connections are made on the second housing. This enables the water chamber and/or enclosing housing to be removed/engaged in the same slide-off/on motion making refilling of the chamber simpler.

In the first and second preferred embodiments of the present invention, tubular protrusions are provided for making a connection between the humidifier apparatus and a water chamber in order to deliver gases to the chamber and receive humidified gases from the chamber. Preferably the tubular protrusions also include a resilient boot in order to provide an improved seal between the water chamber and the protrusions.

A further embodiment of the present invention is envisaged wherein the connections between the apparatus manifold and the water chamber are not provided side by side as described in the first and second embodiment of the present invention but rather are provided one within the other, for example the inlet and outlet may be coaxial. Such a configuration would enjoy the same advantages as the configurations described in more detail in the first and second embodiments of the present invention. It is also envisaged that such connections may also include similarly configured tubes for providing pressure measurements or pressure feedback.

While the above preferred embodiments describe male/female type connectors wherein the water chamber has two female connectors for mating with corresponding male connectors of the apparatus manifold, it is envisaged that many variations will present themselves to those skilled in the art without departing from the spirit of the present invention. For example the water chamber may be provided with two male connectors while the apparatus manifold is provided with corresponding female connectors, or the water chamber may be provided with one male and one female connector for connecting to the corresponding male and female connectors of the apparatus manifold. Further it is envisaged that connectors of an androgynous nature may be provided for making connection between the water chamber and the apparatus manifold wherein each connector may include both male type protruding portions and female type recess portions. Such connections may be particularly advantageous when the inlet and outlet is provided one within the other.

With reference to the first and second preferred embodiments of the present invention, some common features of a water chamber suitable for use with either preferred embodiment will now be described in more detail.

The chamber as shown in FIG. **5** is constructed from an open bottomed plastic container enclosed by a heat conductive base **24**, and includes a horizontally aligned gases inlet **27** and a parallel gases outlet **28**. It is envisaged that other configurations of the present invention are possible where the slide-on direction employed to fit the water chamber is not horizontal but at an angle from the horizontal or vertical. In such cases, the gases inlet **27** and outlet **28**, are preferably parallel and aligned with the direction of the intended slide-on motion to allow mating of the chamber inlet/outlet ports and the connection manifold.

The water chamber of the present invention preferably includes an inlet extension tube **30**, and an outlet extension tube **31**, extending inwardly into the chamber interior from the periphery of the chamber wall and preferably having a generally tapering body. The inlet extension tube **30** and the outlet extension tube **31** are preferably moulded from the same clear thermoplastic material as the chamber shell **26**. The inclusion of inlet/outlet extension tubes has been found to significantly reduce noise produced by the airflow around the chamber. Preferably at least one extension tube has an air bleed aperture to aid filling of the chamber with the chamber tipped up. The air bleed is preferably located in the top surface of the extension tube and preferably toward the end of the extension tube which is connected to the chamber wall. Referring to FIG. **6**, preferably the air bleed aperture **33** is positioned such that when the tank is tipped up for filling, the air bleed valve height corresponds with the preferred fill height **32** for the water chamber. This feature aids in preventing overfilling of the water chamber.

Additionally, with reference to FIG. **7**, the extension tubes **30** and **31** may act as a weir against water flow back through the gases inlet and gases outlet, upon tilting of the chamber as shown by water level line **44**. If present, preferably the air bleed aperture **33** is present only on the outlet extension tube **31** and not present in the inlet extension tube **30**. This prevents water back-flow through the inlet port **27** occurring upon tilting of the chamber.

The present invention may further include a downwardly extending central baffle or rib located between the inlet and outlet extension tubes to ensure against gases short circuiting the chamber by flowing directly from the exit of the inlet extension tube **34**, to the entry of the outlet extension tube **35**. With the baffle the gases are forced to follow a more tortuous path ensuring adequate humidification during their journey through the chamber.

In use air is received into the chamber via inlet port **27** and travels down the inlet extension tube **30**. On exiting the inlet extension tube **30** air enters the chamber where it is humidified by the evaporation of water from the water supply. Humidified air flows from the chamber through the outlet extension tube **31** and exits through outlet port **28**. The above described flow path is illustrated in FIG. **5** by the arrow **45**.

Although the preceding description gives details of preferred embodiments having parallel and adjacent circular inlet/outlet ports, it is envisaged that other configurations are possible without departing from the spirit of the invention. For example the inlet/outlet ports of the chamber and connection manifold may have a noncircular cross section and not be symmetrical. Further it is possible that the position of the inlet port with respect to the outlet may take one of many alternative configurations. For example the ports and there corresponding connections may also be co-axial or off-set, one inside the other.

Referring to FIGS. **8**–**10**, for ease of assembly the inlet and outlet extension tubes are preferably provided as a snap fit to their respective water chamber inlet or outlet, so that they can be pushed into the chamber through the inlet or outlet and, upon application of sufficient force, snap into a substantially watertight and secure condition.

To this end the inlet **27** and outlet **28** ports of the water chamber may be provided with an inwardly perpendicularly extending annular flange **36** at the inner end thereof and the inlet/outlet extension tubes **38** may include similar perpendicularly outwardly extending flanges **37** from one end of the generally tapering tubular body **46**. The flanges act together as sealing flanges in the fitted and assembled

condition. To retain the extension tubes in the assembled condition, against both translational and rotational movement several securing mechanisms may be provided. In each case the securing mechanisms may be provided on either of the inlet/outlet (of the chamber) or the inlet/outlet extension tube. However it is preferred that they be on the extension tubes, as both components are intended for injection moulding and injection moulding of certain protrusions on the inner surface of the chamber inlet/outlet would be considerably more difficult than on the outer surface of the extension tubes. To secure the tubes against translational movement, and in a sealing condition between the sealing flanges, a plurality of retaining clip protrusions **39** may be provided spaced around the circumference of the tubular body of the extension tubes which co-operate with the inlet/outlet flange **36**. Particularly for ease of manufacture, and ensuring a simple two part injection mould, a notch **42** is allowed in the flange **37** of the extension tubes **38** adjacent the protrusion **39**.

To retain the extension tubes against rotational movement when snap fitted into location, one or more locating protrusions **40** may be provided circumferentially distributed on the outer surface of the tubular body adjacent and contiguous with the outwardly and perpendicularly extending flange **37**. The locating protrusions **40** are preferably generally tapered in both the circumferential and axial direction. Complementary notches **41** are provided in the inwardly extending flanges **36** of the chamber inlet and outlet. In fitting the extension tubes **38** the protrusions **40** are aligned with the notches **41**, and upon full insertion of the tubes, the protrusions **40** enter into a tight frictional fit with the notches **41** ensuring substantial if not complete sealing. It will be appreciated that the mechanism employed to ensure proper location and sealing of the extension tubes into the water chamber may take many forms. Many alternatives will suggest themselves to persons skilled in the art such as glued joints, various forms of plastic welding and various configurations of clipping means and protrusions. The above description is of one particular preferred embodiment and is not meant to be in any way limiting.

It will be readily appreciated that the construction of the water chamber as described is simple to manufacture and each of the plastic components is itself capable of simple injection moulding. Consequently a water chamber according to the present invention is, while providing significant advantages, not significantly more expensive than existing chambers.

The invention claimed is:

1. An apparatus for use in humidified gases delivery treatment comprising:

a housing,

a pressurised gases supply within said housing,

a pressurised gases outlet in said housing in fluid connection with said pressurised gases supply and adapted to make fluid connection with an inlet of a humidifier in order to provide gases flow to a said humidifier,

a humidified gases return in said housing, adapted to make fluid connection with an outlet of a said humidifier in order to receive humidified gases from said humidifier,

a patient outlet in said housing, in fluid connection with said humidified gases return in order to receive humidified gases from said humidified gases return and provide humidified gases to said patient outlet, said patient outlet being in fluid connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient.

2. An apparatus for use in humidified gases delivery treatment as claimed in claim **1** wherein a said humidifier is a heatable water chamber, and said apparatus includes,

a chamber heater connected to said housing and, said housing includes a humidifier engagement locating a said humidifier adjacent said chamber heater, said chamber heater adapted to vaporise liquid water in said water chamber in order to provide water vapour to said gases flow passing through said water chamber.

3. An apparatus for use in humidified gases delivery treatment as claimed in claim **2** wherein said water chamber has a base, and said water chamber is engagable with said humidifier engagement via a single motion, and said single motion of engagement urges the base of said water chamber adjacent and in contact with said chamber heater and makes a first fluid connection between said pressurised gases outlet and said humidifier inlet, and makes a second fluid connection between said humidified gases return and said humidifier outlet, with said first and second fluid connections being made in the direction of said single motion.

4. An apparatus for use in humidified gases delivery treatment as claimed in claim **3** wherein said pressurised gases outlet and said inlet of a said humidifier have between them first complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of the mate and female connectors,

said humidified gases return and said outlet of said humidifier have between them second complementary male and female connectors, having a preferred insertion direction for completing a fluid connection by engagement of the male and female connectors, said preferred insertion direction of said first connectors being the same as said preferred insertion direction of said second connectors, and being the same as at least the direction of a terminal part of said single motion.

5. An apparatus for use in humidified gases delivery treatment as claimed in claim **4** wherein said inlet of said humidifier and said outlet of said humidifier are each a female port,

and said preastuised gases outlet and said humidified gases return are each a resilient tubular projection fitting within respective female ports with said water chamber engaged.

6. An apparatus for use in humidified gases delivery treatment as claimed in claim **5** wherein said tubular projections of said pressurised gases outlet and humidified gases return have substantially parallel axes of extension, said chamber heater includes a substantially planar heating plate, and said axes of extension of said tubes are at least substantially parallel with said insertion direction.

7. An apparatus for use in humidified gases delivery treatment as claimed in any one of claims **1**–**6** wherein said patient outlet includes a connector for receiving a breathing hose and at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electrical or pneumatic connectors.

* * * * *

EXHIBIT 9

US006398197B1

(12) **United States Patent**
Dickinson et al.

(10) **Patent No.: US 6,398,197 B1**
(45) **Date of Patent: Jun. 4, 2002**

(54) **WATER CHAMBER**

(75) Inventors: **Philip John Dickinson**; **David Wixey**, both of Auckland (NZ)

(73) Assignee: **Fisher & Paykel Limited**, Auckland (NZ)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/564,508**

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(30) **Foreign Application Priority Data**

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(52) **U.S. Cl.** **261/141**; 261/30; 261/72.1; 261/119.1; 261/DIG. 65
(58) **Field of Search** ..... 261/30, 72.1, 141, 261/142, 119.1, DIG. 65; 96/367, 370

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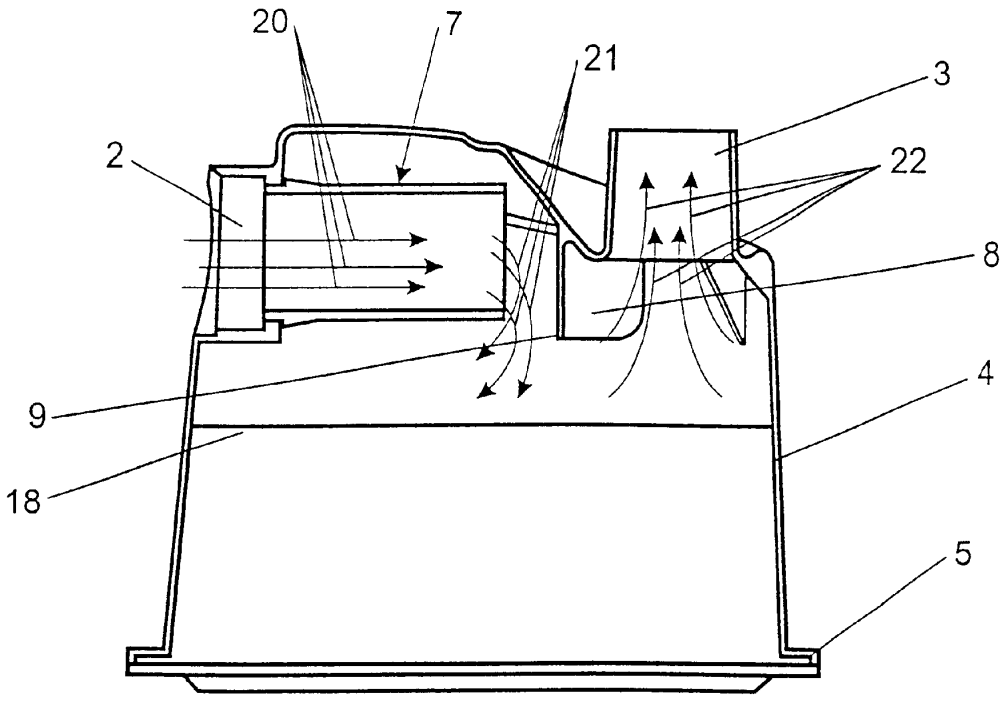
Primary Examiner—C. Scott Bushey
(74) *Attorney, Agent, or Firm*—Trexler, Bushnell, Giangiorgi, Blackstone & Marr, Ltd.

(57) **ABSTRACT**

A water chamber has a horizontally orientated gas inlet with an elongate flow tube extending into the water chamber from the inner periphery of the gases inlet. An inlet end of the elongate flow tube covers the inlet and an outlet end of the flow tube is spaced from the wall of the chamber. In use the flow tube receives gases supplied to the gases inlet, the gases pass through the flow tube and exit the flow tube at the outlet end distant from the wall.

20 Claims, 3 Drawing Sheets



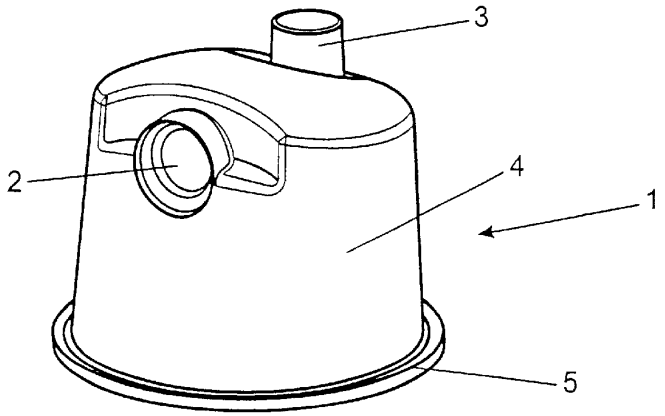


FIGURE 1

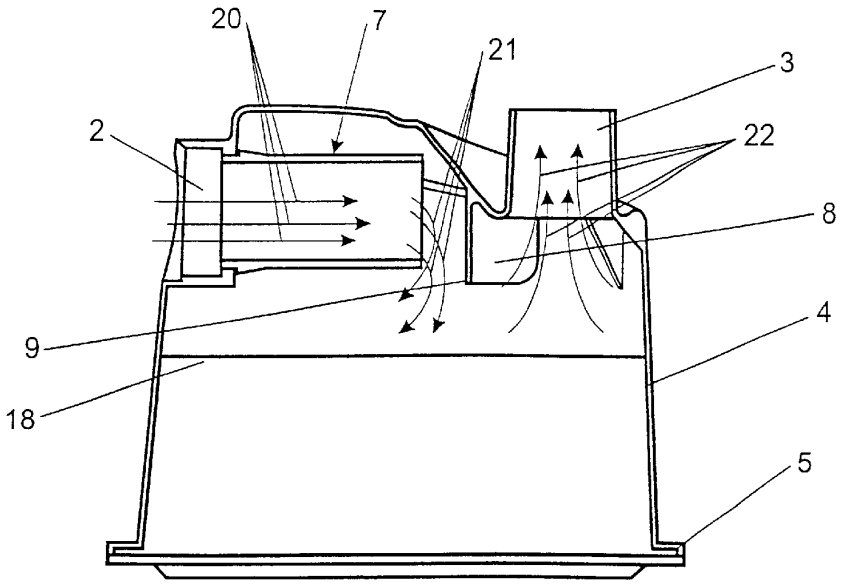


FIGURE 2

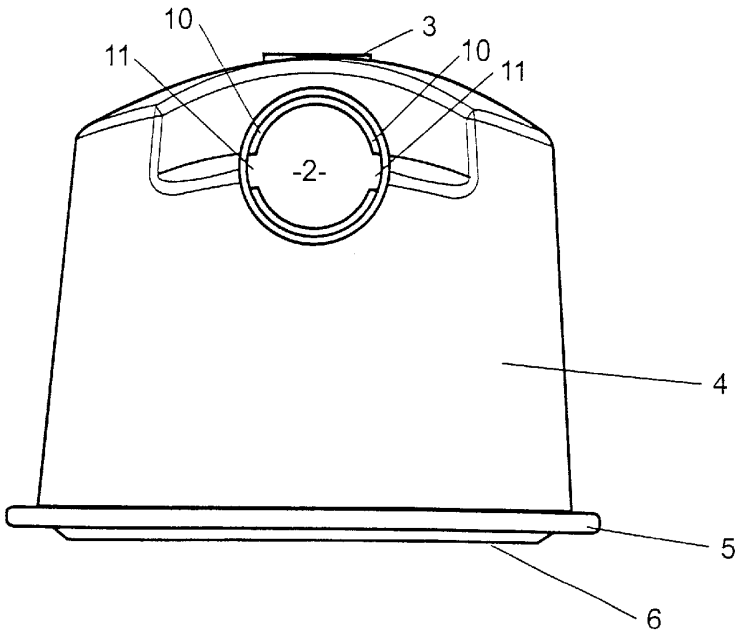


FIGURE 3

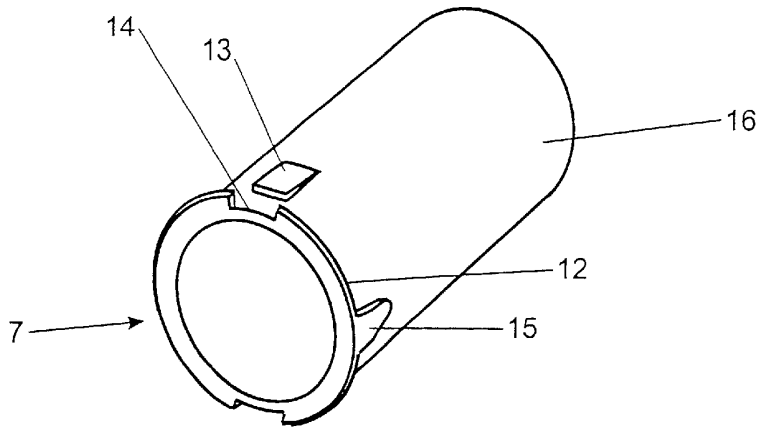


FIGURE 4

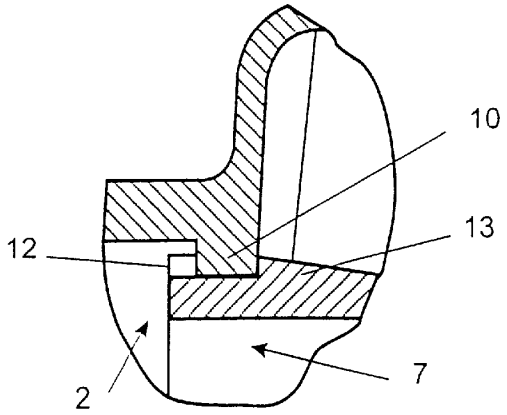


FIGURE 5

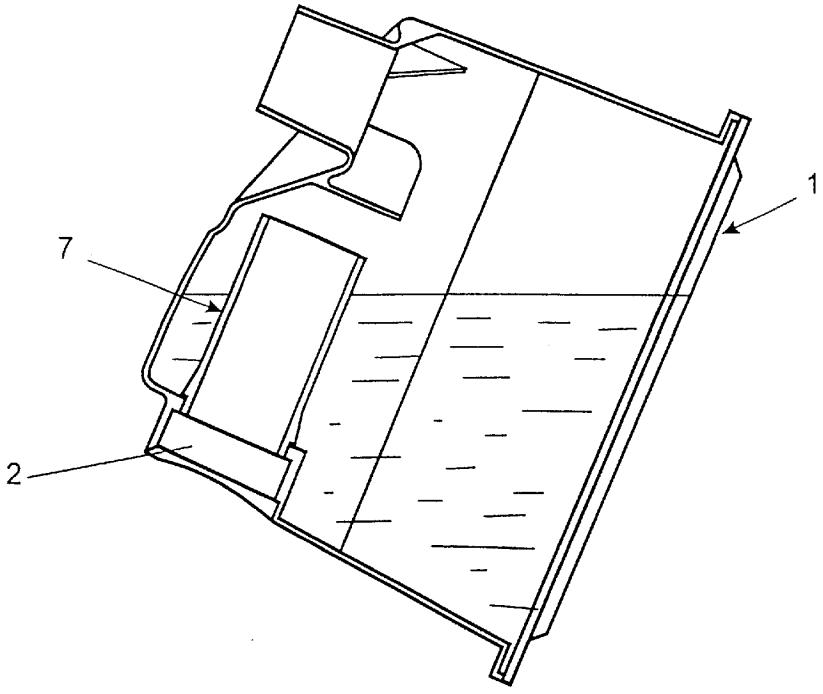


FIGURE 6

WATER CHAMBER

BACKGROUND TO THE INVENTION

i) Field of the Invention

The present invention relates to water chambers for gases humidification and in particular to water chambers for "slide-on" humidifiers and CPAP machines.

ii) Summary of the Prior Art

In the prior art humidification systems are well known which include a heater base and a disposable humidifier chamber which is fitted onto the heater base and within which a supply of water can be heated by the heater base. Air passing through the chamber from an inlet to an outlet is humidified by the evaporation of water from the water supply.

Humidifier chambers of this type are also now used in compact and portable ventilation machines, for example machines intended for the home treatment of obstructive sleep apnoea (CPAP machines). These machines pose a particular difficulty as the air flow is delivered directly to the humidifier chamber from the air blower of the CPAP machine and this can generate an annoying noise level within the humidifier chamber. Furthermore where the CPAP machine is adapted for use with slide-on humidifier chambers, and the connection of the chamber to the machine is accomplished within the single sliding movement, the inlet air port is consequently provided horizontally through a side of the chamber. Locating the inlet port in the side of the chamber significantly increases the likelihood of water spillage from the chamber if the chamber is tilted with water therein. This can be of particular disadvantage where the water may flow out through the inlet port and into the air blower of the CPAP machine.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a water chamber which at least goes some way towards overcoming the above disadvantages or which will at least provide the public with a useful choice.

In a first aspect the invention consists in a water chamber adapted for use in conjunction with a heater base and having a horizontally oriented gases inlet in a wall thereof the improvement comprising an elongate flow tube extending into said water chamber from the inner periphery of said gases inlet, an inlet end of said elongate flow tube covering said inlet and an outlet end of said flow tube being spaced from the wall of said chamber, said flow tube in use receiving, at said inlet end, gases supplied to said gases inlet, said gases passing through said flow tube and exiting said flow tube at said outlet end distant from said wall.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a water chamber according to the preferred embodiment of the present invention,

FIG. **2** is a cross sectional side elevation of the chamber of FIG. **1**,

FIG. **3** is a front elevation of the chamber of FIG. **2** before insertion of the inlet extension tube,

FIG. **4** is a perspective view of an extension tube according to the preferred embodiment of the present invention,

FIG. **5** is a cross sectional side elevation detail of engagement of the extension tube of FIG. **4** with the sealing flange of the chamber inlet, and

FIG. **6** is a cross sectional side elevation of the chamber of FIG. **1** in use with water therein and in a tilted condition demonstrating the operation of the inlet extension tube **7** in reducing the capacity for leakage through the gases inlet **2**.

DETAILED DESCRIPTION

Referring to FIGS. **1** and **2** a water chamber is illustrated particularly for use in a portable CPAP machine adapted to receive slide-on chambers and which makes the gases inlet connection to the chamber in the same slide-on motion. The chamber **1** has a transparent plastic shell **4** and a heat conductive base **6**. The shell **1** and heat conductive base **6** are connected at a peripheral flange **5** which also serves as a securing flange in the slide-on connection with the CPAP machine. The chamber includes a horizontally aligned gases inlet **2** which in use fits over a blower nozzle of the CPAP machine. A gases outlet **3** is provided in the roof of the chamber **1**. The gases outlet **3** may be adapted to take standard breathing circuit fittings.

Referring to FIG. **2** the water chamber **1** is shown in cross section. In the present invention the water chamber **1** includes an inlet extension tube **7** extending inwardly into the chamber interior from the periphery of the gases inlet **2**. In the most preferred embodiment the chamber further includes a curved downwardly extending baffle **8** located between the gases outlet **3** and the termination of the inlet extension tube **7** to ensure against gases short circuiting the chamber by flowing directly from the extension **7** to the outlet **3**. With the baffle **8** in place the gases are forced to follow a more tortuous path ensuring adequate humidification during their journey through the chamber **1**.

The lower edge **9** of the baffle **8** preferably extends lower than the lower edge of the inlet extension tube **7**.

A narrow rib **18** may be provided on the inside wall of the clear plastic shell **4** which will show visually from the outside of the shell to act as an optimum water level "fill" marker.

In use air is received from the blower of the CPAP machine, or if the chamber is used in a standard humidification circuit, then from the ventilator, through inlet **2**. Travelling through the inlet extension tube **7** the air is imparted with a more controlled laminar flow than is generally provided by the blower, as indicated by arrows **20**. On exiting the inlet extension tube **7** the air is deflected by the baffle **8** to the various environs of the water chamber as indicated by arrows **21**. Air eventually leaves the chamber through outlet **3** as indicated by arrows **22**.

By providing the inlet extension tube **7** and therefore imparting an improved flow pattern to the inlet flow, it has been found that the noise level of the humidifier chamber has been significantly reduced, and, in conjunction with the curved baffle **8**, effective operation of the water chamber **1** has been maintained. Additionally, with reference to FIG. **6**, the inlet extension tube **7** acts as a weir against water flow back through gases inlet **2** upon tilting of the chamber **1**.

These benefits have been achieved while maintaining, in the design shown, S equivalent external appearance and size, and the same ease of use and simplicity to the user, as earlier chambers.

Referring now to FIGS. **3–5**, these depict the preferred embodiment of the present invention, and in particular the

detail of the connection between the inlet extension tube **7** and the plastic shell **1**. Note that the inlet extension tube **7** is preferably moulded from the same clear thermoplastic material as the chamber shell **4**.

For ease of assembly the extension tube **7** is preferably provided as a snap fit to the inlet **2**, so that it can be pushed into the chamber through the inlet **2** and, upon application of sufficient force, snap into a substantially watertight and secure condition.

To these ends the inlet **2** is provided with an inwardly perpendicularly extending annular flange **10** at the inner end thereof The inlet extension tube **7** includes a similar perpendicularly outwardly extending flange **12** from one end of the generally tapering tubular body **16**. The flanges **10** and **12** act together as sealing flanges in the fitted and assembled condition as shown in FIGS. **2** and **5**.

To retain the extension tube **7** in the assembled condition, against both translational and rotational movement several securing mechanisms are provided In each case the securing mechanism may be provided on either of the inlet **2** or the inlet extension tube **7**, however it is preferred that they be on the inlet extension tube **7**, as both components are intended for injection moulding and injection moulding of certain protrusions on the inner surface of the inlet **2** would be considerably more difficult than on the outer surface of the tube **7**.

To secure the tube **7** against translational movement, and in a sealing condition between the sealing flanges **10**, **12** a plurality (preferably two) of remaining clip protrusions **13** are provided spaced around the circumference of the tubular body **16** of the extension tube **7** adjacent but spaced from the flange **12**. The protrusions **13** are preferably spaced from the flange **12** at a distance correlating to the thickness of flange **10**. In use, as depicted in the detail FIG. **5** the flange **10** is secured between an upstanding edge of the protrusion **13** and the leading face of the flange **12**.

Particularly for case of manufacture, and ensuring a simple two part injection mould, a notch **14** is allowed in the flange **12** of the tubular extension **7** adjacent the protrusion **13**.

To retain the tubular extension **7** against rotational movement when snap fitted into location one or more, preferably **2**, locating protrusions **15** are provided circumferentially distrbuted on the outer surface of the tubular body **16** of the inlet extension tube **7**, adjacent and contiguous with the outwardly and perpendicularly extending flange **12**. The locating protrusions **15** are preferably generally tapered in both the circumferential and axial direction. Complementary notches **11** are provided in the inwardly extending flange **10** of the inlet **2**. In fitting the inlet extension tube **7** the protrusions **15** are aligned with the notches **11**, and upon fill insertion of the tube **7** the protrusions **15** enter into a tight frictional fit with the notches **11** ensuring substantial if not complete sealing. Given their particular configuration the protrusions **15** could be readily provided on the inner surface of the inlet **2** in which case complementary notches would instead be provided on the flange **12** of the inlet extension tube **7**.

It will be readily appreciated that the construction as described is simple to manufacture and each of the plastic components is itself capable of simple injection moulding. Consequently a water chamber according to the present invention is, while providing significant advantages, not significantly more expensive than existing chambers.

What is claimed is:

1. In a water chamber adapted for use in conjunction with a heater base and having a horizontally oriented gases inlet in a wall thereof the improvement comprising an elongate flow tube extending into said water chamber from the inner periphery of said gases inlet, an inlet end of said elongate flow tube covering said inlet and an outlet end of said flow tube being spaced from the wall of said chamber, said flow tube in use receiving, at said inlet end, gases supplied to said gases inlet, said gases passing through said flow tube and exiting said flow tube at said outlet end distant from said wall.

2. A water chamber as claimed in claim **1** wherein said flow tube extends for a distance of at least a quarter of the diameter of said water chamber.

3. A water chamber as claimed in claim **2** wherein said gases inlet and said flow tube are aligned radially and said flow tube extends to approximately the middle of said chamber.

4. A water chamber as claimed in claim **1** wherein said chamber includes a vertically oriented gases outlet in the roof of said chamber, said gases outlet located beyond the termination of said flow tube, and a baffle wall extending downwardly from the roof of said chamber between the outlet end of said flow tube and said gases outlet.

5. A water chamber as claimed in claim **4** wherein said baffle wall is curved to be closest to said flow tube at the centre thereof, the ends of said baffle wall curved away from said flow tube.

6. A water chamber as claimed in claim **1** wherein said water chamber comprises a transparent plastic shell open at the bottom and having a peripheral flange, a heat conductive plate enclosing said bottom of said shell and sealed at its periphery to said flange, and said elongate flow tube comprises a tubular extension tube member fitted at said gases inlet.

7. A water chamber as claimed in claim **6** wherein said extension tube includes a perpendicularly extending sealing flange at one end thereof, and said gases inlet of said water chamber includes a perpendicularly and inwardly extending annular, sealing flange, and said sealing flange of said extension tube and said sealing flange of said water chamber inlet abut one another in an assembled condition.

8. A water chamber as claimed in claim **7** wherein either said extension tube or said gases inlet includes a plurality of retaining protrusions spaced around the circumference thereof, adjacent but spaced from the respective said sealing flange such that in an assembled condition said protrusions and the said adjacent sealing flange engage the other said sealing flange therebetween.

9. A water chamber as claimed in claim **8** wherein said adjacent sealing flange includes a notch in the vicinity of each said retaining protrusion.

10. A water chamber as claimed in claim **7** wherein either said extension tube or said gases inlet to said water chamber includes one or more locating protrusions around the circumference thereof adjacent to and contiguous with their respective sealing flange, and the other said sealing flange includes one or more corresponding notches into which said retaining protrusions engage to restrain said extension tube against rotational movement.

11. A water chamber as claimed in claims **3** wherein said chamber includes a vertically oriented gases outlet in the roof of said chamber, said gases outlet located beyond the termination of said flow tube, and a baffle wall extending downwardly from the roof of said chamber between the outlet end of said flow tube and said gases outlet.

12. A water chamber as claimed in claim **11** wherein said baffle wall is curved to be closest to said flow tube at the centre thereof, the ends of said baffle wall curved away from said flow tube.

13. A water chamber as claimed in claim 3 wherein said water chamber comprises a transparent plastic shell open at the bottom and having a peripheral flange, a heat conductive plate enclosing said bottom of said shell and sealed at its periphery to said flange, and said elongate flow tube comprises a tubular extension tube member fitted at said gases inlet.

14. A water chamber as claimed in claim 13 wherein said extension tube includes a perpendicularly extending sealing flange at one end thereof, and said gases inlet of said water chamber includes a perpendicularly and inwardly extending annular sealing flange, and said sealing flange of said extension tube and said sealing flange of said water chamber inlet abut one another in an assembled condition.

15. A water chamber as claimed in claim 4 wherein said water chamber comprises a transparent plastic shell open at the bottom and having a peripheral flange, a heat conductive plate enclosing said bottom of said shell and sealed at its periphery to said flange, and said elongate flow tube comprises a tubular extension tube member fitted at said gases inlet.

16. A water chamber as claimed in claim 15 wherein said extension tube includes a perpendicularly extending sealing flange at one end thereof, and said gases inlet of said water chamber includes a perpendicularly and inwardly extending annular sealing flange, and said sealing flange of said extension tube and said sealing flange of said water chamber inlet abut one another in an assembled condition.

17. A water chamber as claimed in claim 16 wherein either said extension tube or said gases inlet includes a plurality of retaining protrusions spaced around the circumference thereof, adjacent but spaced from the respective said sealing flange such that in an assembled condition said protrusions and the said adjacent sealing flange engage the other said sealing flange therebetween.

18. A water chamber as claimed in claim 15 wherein either said extension tube or said gases inlet to said water chamber includes one or more locating protrusions around the circumference thereof adjacent to and contiguous with their respective sealing flange, and the other said sealing flange includes one or more corresponding notches into which said retaining protrusions engage to restrain said extension tube against rotational movement.

19. A water chamber as claimed in claim 7 wherein either said extension tube or said gases inlet to said water chamber includes one or more locating protrusions around the circumference thereof adjacent to and contiguous with their respective sealing flange, and the other said sealing flange includes one or more corresponding notches into which said retaining protrusions engage to restrain said extension tube against rotational movement.

20. A water chamber as claimed in claim 8 wherein either said extension tube or said gases inlet to said water chamber includes one or more locating protrusions around the circumference thereof adjacent to and contiguous with their respective sealing flange, and the other said sealing flange includes one or more corresponding notches into which said retaining protrusions engage to restrain said extension tube against rotational movement.

* * * * *